SAFER 1 Research Programme
Support and Assessment for Fall Emergency Referrals:
Evaluation of the costs and benefits of computerised on-scene decision support for emergency ambulance personnel to assess and plan appropriate care for older people who have fallen

Final Study Report:
Date of Submission 13 October 2011

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Acknowledgements

The SAFER 1 research team thanks the Department of Health Policy Research Programme’s Information and Communication Technology Research Initiative (ICTRI 2) for funding this study, and the Wales Office for Research and Development in health and social care for funding excess treatment costs, service support costs and a research professional to support the study in Wales. We also thank the participating ambulance services of Welsh Ambulance Services NHS Trust and the East of England Ambulance Service NHS Trust, the paramedics who volunteered to participate, and Age Concern and other falls services that supported the study.

We are grateful to Patients and Service Users for their support and contributing at various stages – not least in reviewing study materials.

We acknowledge also the input of the Secure Anonymised Information Linkage (SAIL) team at Swansea University for their contribution to the information management of the study.

Without the commitment of all these groups and individuals this complex research would not have been possible.

This is an independent report commissioned and funded by the Department of Health Information and Communication Technology Research Initiative (ICTRI 2). The views expressed are not necessarily those of the Department.
Executive Summary

Background

Emergency (999) calls to the ambulance service are rising relentlessly. With an ageing population and burden of chronic conditions, finding appropriate ways of responding to patients who do not need or benefit from care at an Emergency Department (ED) is a policy priority in the UK and across developed healthcare systems. Falls in older people have become an increasing problem for which community based services may be more clinically effective than treatment in secondary care. In particular, falls service care has been shown to improve health outcomes in patients who have been attended by an emergency ambulance for a fall over the following year. However, emergency ambulance services have not traditionally provided a range of responses that suit patients across the spectrum of need, and ambulance crews have not been trained to make decisions to leave people at home rather than taking them to the ED. Computerised decision support tools have been used in other settings to help practitioners assess, triage and plan care for patients but are untested in the emergency prehospital setting.

The Support and Assessment for Fall Emergency Referrals (SAFER) 1 trial was designed to fill this gap in evidence, and was funded through the Department of Health Policy Research Programme’s Information and Communication Technology research call focused on the care of people with chronic conditions. In this report we present the methods and results related to the clinical and cost effectiveness of Computerised Clinical Decision Support (CCDS) software for use by paramedics when attending older people who have had a fall and for whom a 999 call has been made.

Intervention

The health technology being evaluated was an application of CCDS on a hand-held Tablet PC for use on scene by ambulance crews to make decisions about the clinical and social care needs of older patients who had fallen and generated a call to the emergency ambulance service. Clinical and technology-based training formed the other key component of the intervention. The CCDS sat alongside an electronic patient report form used for patient related documentation. The CCDS was to be used to assess whether the older person who had fallen should be taken to the ED or offered an alternative care plan.

Paramedics in the control group were trained in assessment skills for leaving patients at home (rather than taking them to the ED); protocols and decision support tools were paper-based; a response to falls including multi disciplinary assessment was available within 5 days.

Objectives

To estimate the effects of the health technology at one month on:

The objectives of the trial were to estimate the effects of the intervention at one month on:

1. Pathway of care following attendance by an emergency ambulance paramedic for a fall
   - Referrals to falls service
   - Non-conveyance (ED avoidance)
2. Time to first subsequent emergency healthcare contact for a fall, or death
3. Time to first subsequent emergency healthcare contact for any reason, or death (‘event-free period’)
4. Event-free period adjusted by health-related quality of life
5. Quality of life of patients, including ‘fear of falling’, independence and satisfaction
6. Subsequent falls and fractures
7. Clinical and operational ‘process’ indicators:
   - Compliance with protocols including CCDS usage
   - Job cycle times – from 999 call to ‘ambulance free’ time
Length of emergency care episode – from 999 call to discharge of patient from ED or ambulance if not conveyed

8. NHS resource use

and at each participating site, to explore:

- implementation issues with service providers
- patient experience and views of the intervention

**Methods**

Cluster randomised trial with qualitative component in two sites: paramedics randomly allocated to the intervention group were trained and issued with the hardware and software required for the trial, for use with older people who had fallen; and paramedics randomly allocated to the control group continued with standard care. Patients aged 65 or over in the trial catchment areas, for whom a call to the emergency ambulance service was coded by the call-taker as a fall, were eligible.

**Results**

**Trial implementation**

Lessons were learned from the trial implementation which was lengthy and challenging. Conducting randomised controlled trials in health services research can be complex and difficult. This is especially true in pre-hospital emergency care where implementation, randomisation and recruitment in a stressful clinical environment present particular challenges. However, better evidence is needed to support good clinical practice in pre-hospital care. We have used a qualitative approach to describe challenges and solutions encountered in conducting a RCT of a pre-hospital computerised falls assessment and referral system in 2 UK ambulance services. The main challenges were development of a complex intervention, recruitment and retention of study sites, implementation of the intervention, and data collection and management processes. Several key policy changes before the trial commenced affected all of these issues. The conflicts between maintaining operational performance and conducting research within an ambulance service, the complex relationships between multiple stakeholders, external events and engaging management support led to significant delays in trial implementation. Study costs also escalated. Factors which helped resolve problems included developing project management strategies to tackle specific issues, engaging ambulance service paramedics in protocol development and data capture and funding designated ambulance service personnel to link study services and the research team. The experience has shown that it is possible to conduct RCTs in pre-hospital care but future trials can be improved by continued development of research capacity within ambulance services and aligning research activity with strategic priorities and service objectives.

**Clinical Effectiveness**

Forty two paramedics volunteered to participate in the trial; 779 patients were included for analysis. There were no differences in participant characteristics between sites, in age, sex or incident type, although the proportion of participants trial arms varied by site (site 1 - intervention to controls 54:46; site 2 - 66:34). Reported CCDS usage was low at 12% (n = 54) of intervention group patients, although higher at site 2 than site 1 (24% versus 2%).

We found no differences between intervention and control groups in subsequent emergency healthcare contacts or death related to a fall or for any reason, or patient reported falls, quality of life, satisfaction or fear of falling.

However, the proportion of patients referred to falls services was significantly higher in the intervention group than in the control group [adjusted proportions: 31/436 (7%) versus 13/343 (4%); risk estimate 2.04 with 95% CI from 1.12 to 3.71]. The associated higher non-
conveyance rate did not reach statistical significance [adjusted rates 179/436 (41%) versus 131/343 (38%); risk estimate 1.13 with 95% CI from 0.84 to 1.52] and showed considerable differences between sites. Job cycle time was lengthened by 8.55 minutes (95% CI 2.09 to 15.01). No differences were found in clinical documentation levels which were high (>90%) in both arms of the trial.

Reported CCDS usage varied widely between individual paramedics (0 – 22 times) but was associated with: non-conveyance [CCDS used = 35/54 (65%) not conveyed versus 274/726 (38%)]; patient referred to falls service [CCDS used = 12/54 (22%) versus 47/726 (7%)]; and job cycle times increased by 10.9 minutes (95% CI from 0.5 to 14.4), again with several differences between sites.

**Cost Effectiveness**

We estimated the mean cost of implementing the CCDS intervention as £154 per patient recruited; and that of emergency health care as £2981 in the intervention group and £2567 in the control group. Though not itself significant (p = 0.22), this difference includes a significant difference in the cost of referrals to falls services (p = 0.014). Thus over 30 days, the costs of the SAFER 1 intervention were not offset by reductions in emergency health care use or improved health-related quality of life. However limiting follow-up to 30 days omits the medium- and long-term effects of the intervention, notably referrals to falls services. So our analysis could not detect any of the benefits of this pathway.

Fortunately Logan’s concurrent randomised trial to evaluate referrals to falls services found major improvements in the numbers of falls and fall-related ambulance trips per person over 12 months, and scores on the Nottingham Index of Activities of Daily Living and the Falls Efficacy Scale. Hence the doubling of falls referrals in SAFER 1 at a cost of £154 per patient, coupled with Logan’s positive findings on falls service referrals, is more promising. We are therefore constructing an economic model to quantify this inference.

**Stakeholder views - qualitative strand**

*Patients and carers:* The analysis revealed a range of views about paramedics using CCDS. Some were supportive, some raised concerns about taking focus away from patients, and affecting confidence in practitioners. There was a strong presumption that personal health data howsoever held was properly protected. No objections relating to the security of data held electronically were raised.

*Paramedics:* Before the trial began, the dominant view in the data was that participation in SAFER 1 offered paramedics developmental opportunities to receive training, to improve their ability to do a good job - for the service and patients - and to provide better access to clinical information. Following the trial period, intervention paramedics reported varied experiences of use, largely depending on local factors including system configuration. The CCDS was associated with positive influences on how paramedics make decisions. Some advantages relating to electronic data capture, access to clinical guidelines, new pathways of care, and the potential to improve patient care and data transfer, were also evident. The main challenges to use arose from hardware and non-integrated software, increased time on scene, and reliability of organisational support.

*NHS Stakeholders (ambulance service and partner service managers):* The use of the technology was seen to have substantial benefits for the service and for patients. Strategies to meet the challenges of implementation were improved communication, refining the CCDS software to be more user-friendly, resolution of logistical, connectivity and hardware issues, and the development of robust systems to maintain continuity of support. The main operational issues at both sites were balancing the need to meet existing standards with developing new equipment and working practices that may benefit patients and service providers in the future.
Limitations

Challenges related to changes in policy, ethics, research and information governance requirements and processes and the emergency prehospital operational context led to some changes to the study design. The trial only included a short term outcomes (at 1 month) which, although it provided a useful indicator of the safety of the new health technology (risks would be mainly associated with non-conveyance and would result in further emergency episodes or death in the short term), would be unlikely to detect longer term health benefits associated with the effects of care provided by the falls service. The intervention was not fully integrated with the electronic data capture systems in place for the trial and there were usability problems that resulted in lengthened on-scene times and low usage, reducing the power of the trial to detect effects on health outcomes.

Qualitative data were collected from a range of stakeholders but through a mix of methods – individual face to face semi-structured interviews; telephone semi-structured interviews and focus groups – which is not ideal in one dataset. However, the number of participants across services and stakeholders strengthens the findings reported.

Conclusions

The SAFER 1 trial has delivered encouraging results related to the implementation and effects of CCDS in prehospital emergency care, especially on processes of care of older people who have a fall and call 999. The trial was undertaken in two ambulance services in England and Wales and was close to meeting its revised sample size.

Although no effects were found on health outcomes, our principal process outcome of pathway of care following the emergency attendance showed that referrals to falls services were doubled in the intervention group. Linking these findings on referrals with recent closely related research findings from Logan [1] about substantial benefits of such referrals indicates that the CCDS is likely to generate worthwhile clinical benefits over a longer follow up period.

When the CCDS was implemented, quantitative and qualitative findings are encouraging in a context where the CCDS was implemented, due to circumstances, without full integration with electronic data capture, and with known limitations in usability. Patients, paramedics and stakeholders within the ambulance and partner services were supportive of the intervention in principle, and the intervention did impact on paramedic practice, both when it was actively used, and more widely, in the group of paramedics trained in its usage.

With further development of usability, including integration with electronic data capture systems, which are evolving all the time in the UK prehospital emergency care setting, these results indicate that CCDS may provide a very useful tool to support paramedics in changing practice and benefitting patients.

Based on these results we recommend that further investment is made to develop CCDS for use in prehospital emergency care, to be more user-friendly, and to integrate the decision support software with other software designed to capture patient-related data at the scene of 999 calls. In particular we propose that integrated CCDS-ePRF systems are then tested for patients who have suffered falls or have other conditions that may not need immediate care at the ED, with appropriate piloting and then through further fully powered multi centred RCT, with ambulance and partner NHS services who are fully committed to delivering such a trial. In the meantime, evidence about the cost–effectiveness of training, paper-based protocols and access to falls referral pathways is being gathered through a parallel multi centred NIHR HTA funded trial, SAFER 2.

In short, given the evidence that CCDS does not put patients at risk, and its low cost, we judge that the resulting increase in referrals to falls services is likely to benefit older people who fall and yield value for money.
References

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Chapter 1 Introduction

Introduction

In this introductory chapter to the final report to the commissioners for the Support and Assessment for Fall Emergency Referrals (SAFER) 1 trial, we outline the background to the study: the programme through which the trial was funded; the broad policy context for the trial; and the format of the report.

Commissioning brief

The SAFER 1 trial was commissioned through the Department of Health’s Policy Research Programme themed call on Information technology and chronic disease management: ICTRI 2 http://www.ictri.port.ac.uk/ictri2/index.htm

The rationale for the call was based on the World Health Organisation’s identification of chronic conditions as the leading cause of disability by 2020. The response to this problem has been a drive towards detecting, in a more proactive way, illness in the community, and to intervene in cost-effective ways to improve the quality of life of the individuals concerned. This new approach to the delivery of care, based on the premise that people in need of care should be able to remain independent and participate in their community as much as, and for as long as possible, was given as background to the call. The brief highlighted the need to increasingly deliver care where it is most appropriate; potentially anywhere in normal physical environments - a possibility, for example, in the user’s home or in a ‘lower intensity’ care setting, through “telecare”.

Potential benefits of these new models of care were outlined - improvements in quality of life, efficiency gains to health and social care systems by reducing ‘just-in-case’ admissions to hospital and residential care.

Collaborations across research communities were encouraged, to provide evidence that will contribute to both policy and to practice development.

Key objectives of this research included providing:

- A description and definition of the new method of care and its role in whole care systems
- Description and clarification of links to existing government policy and initiatives
- An understanding of systemic issues such as sustainable business and delivery models, service commissioning and governance and workforce training and development
- An understanding of stakeholder issues such as the perceptions of patients, informal carers and professionals, especially with regard to the relationship between design, use and the utility of technologies.
- An understanding of the different (Information and Communications Technology (ICT)-based) communication needs of different health practitioners and the translation and use of patient information across different contexts
- An understanding of the role of the private sector both those inside and outside the immediate National Programme for Information Technologies (NPfIT) supply chain and those supplying care services.

Six projects of varying lengths were commissioned across a range of topics to provide more evidence on the role of ICT in healthcare and effects on quality of care and ultimately the quality of life of patients using ICT solutions for their health needs:

1. Integrating telecare systems for chronic disease management in the community: What needs to be done?
   
   Prof Carl May et al (Newcastle), Prof Frances Mair (University of Glasgow), & Prof Anne Rogers et al (University of Manchester)
2. The role of networked technology in dementia care.  
   *Lead researcher:* Dr John Powell.  Health Sciences Research Institute, University of Warwick

3. Telemonitoring and self management in hypertension (TASMINH 2):  
   A randomised controlled trial and qualitative evaluation of the efficacy and acceptability of telemonitoring and self management in the control of hypertension.  
   *Lead Researcher:* Dr Richard McManus.  Dept. Primary Care and General Practice, University of Birmingham


5. Supporting the self management of obesity: The role of information and communication technologies.  
   *Lead researcher:* Professor Fiis Henwood.  Social Informatics Research Unit, University of Brighton

6. An evaluation of the costs and benefits of computerised on-scene decision support for emergency ambulance personnel to assess and plan appropriate care for older people who have fallen: randomised controlled trial (SAFER 1).  
   *Lead Researcher:* Professor Helen Snooks.  Centre for Health Information Research and Evaluation, University of Swansea

**Policy context for the SAFER 1 trial: ‘Modernisation’ of NHS**

*Quality improvement*

Initiatives introduced across the NHS over the years have emphasised the need for a patient centred service that is safe and effective. The importance of continuous quality improvement has been demonstrated again and again, often through the detection of adverse incidents. The importance of clinical audit has been recognised, alongside other performance monitoring and benchmarking exercises. Central to all efforts to maintain and improve the quality of care delivered is the availability of clinical and operational management information. Unfortunately, both have been found to be frequently lacking in the prehospital phase of care.

*Accountability*

A key concern for prehospital emergency care is the handover of patients and their care to health professionals who will continue their care. This is usually at the Emergency Department (ED). Handover takes place verbally, with written documentation of prehospital assessments, patient history and circumstances of 999 attendances, as well as treatments given left with the ED staff, to be filed with the patient’s ED record of care. When patients are not conveyed to hospital, or are passed on to the care of another health professional e.g. a GP, this documentation is left with the patient to be handed to other relevant care providers. Ambulance staff report a lack of confidence in the notice that is taken by ED doctors of this prehospital documentation. It has been noted that clinical documentation completed by ambulance crews is frequently missing or incomplete [1]. Accountability for care delivered must rest on the availability of documented assessments, treatment decisions and care provided, but lack of full information suggests that accountability is difficult to demonstrate in these circumstances.

Furthermore, it is known that protocols for treating patients are frequently not followed by ambulance crews, particularly in relation to conveyance to hospital [2]. Leaving patients at the scene of their attendance is common, but not generally permitted by treatment protocol except in the case of a clear refusal to travel by a patient assessed as competent to make this decision. There are some exceptions to this, in particular services for specific conditions e.g. resolved hypoglycaemia; or for personnel with extended skills training e.g. Emergency Care Practitioners. In addition, there has been a move recently, in many services, towards allowing
ambulance crews to make decisions to leave patients at home when criteria are met e.g. for older people who have had a fall. Accountability has been unclear in these situations – and common across many services – where current practice is tacitly approved by ambulance service clinical and operational managers and ED clinicians. Crews have felt unprotected in this ambiguous situation, trying to do their best for patients and for the healthcare system but unsure about their position if anything goes wrong [3].

**Evidence into practice**

With moves across healthcare to deliver care according to the best evidence about clinical and cost effectiveness, the ambulance service has been trying to follow this approach. However, rigorous evidence is lacking for many areas of care, particularly about the best way to treat patients who may not clinically need care at hospital. Evidence about the safety, costs and effects of alternative care pathways is needed urgently [4]. Ambulance services are currently implementing “treat and refer” pathways for several groups of patients including older people who have fallen, people with mental health problems and others, although generally without robust evidence about the potential impact of such changes.

**Electronic data capture in emergency prehospital care**

The current focus in NHS policy and service development on improving quality, safety, and patient experience through performance management and greater accountability of health care provision [5], is partly to be achieved through expansion of electronic data capture and record linkage for patient care, service management, clinical audit and evaluation. This was reiterated within the context of emergency prehospital care through the DH report: "Taking healthcare to the patient" [6]. However, the challenges to successful implementation of information technology in the health service are significant [7], [8] and well documented [9] and are likely to be even more severe in the context of 1) an emergency service and 2) an environment of mobile data capture [10].

Introduction of the CCDS for use by paramedics relies upon the pre-existence – or concurrent introduction - of an electronic patient record (ePR). The two pieces of software should be fully integrated, but the ePR can be introduced without CCDS.

The potential benefits of electronic patient related data capture in healthcare have long been known [11], [12], and prompted the development of a national strategy for information technology (IT) implementation in the NHS (NPiIT). The investment in IT announced in 2002 was of an unprecedented scale and ambition [13], [7] and was perceived from the outset to be, at least challenging, and probably high risk in many respects [13]. Connecting for Health, a key component of NPiIT, has been beset by difficulties. The integral component related to ePR implementation in ambulance services moved to more local development by the 12 Strategic Health Authorities in 2007 and was abandoned as a national initiative, with all further development devolved in 2010, leaving procurement and funding decisions to be made at local level.

Implementation has been found to require functional criteria related to usability, data security, auditability and integrity [14] as well as appropriate consultation and change management [15],[16]. Despite substantial opportunities for improvements in safety, quality and efficiency of healthcare provision, barriers to implementation are numerous, highlighted by Bates and Gawande as: financial; lack of standards; and cultural barriers. These have led to reluctance to invest and delays when programmes have been implemented [17].

There are two main systems of patient related data capture and storage in the ambulance service:

999 call centre where emergency calls are first taken, details recorded, incidents and patients categorised according to the urgency of their condition and responding vehicles then dispatched

Patient clinical records completed by attending front line staff – paramedics; emergency care practitioners; emergency medical technicians etc.
Call centres have been computerised since the early 1990s. The process of computerisation was complex and time crucial, as 999 responses depend on the reliable capture of information, immediate allocation of responding vehicle(s) and communication with mobile crews. A system crash within the London Ambulance Service, where all paper-based back up systems had been banned during the switch to the new computerised system, has become infamous in ICT history. In this case, 999 call handlers were left in the situation of telephoning back people who had placed 999 calls several hours previously to ask whether an ambulance had turned up. Clearly the system crash had major implications for safety and quality of care and has probably ensured a higher degree of caution in IT implementation in ambulance services than might otherwise have been the case [18-20].

Increasingly complex systems for prioritising calls (Advanced Medical Priority Dispatch System; NHS Pathways) have been introduced to allow systematic and consistent categorisation of calls by condition and urgency of required response. Similarly, sophisticated systems have been introduced for keeping response times to a minimum by moving ambulances around dynamically to various standby locations using predictive software, as ambulances are allocated to calls. These systems rest on early work done in the US, pioneered by Jack Stout [21]. This type of coverage has now become standard in UK ambulance call centres. 999 call centre details are passed to crews via radio or GPRS, although patient details are limited – at this point the focus is on speed of response, so the emphasis is on location and access details.

Where electronic systems have been introduced call details can be automatically uploaded into the ePR in real time. Ambulance personnel then complete patient related documentation – traditionally paper based, although some services now have the ePR in place in some areas. A paper copy of the patient record is left with ED staff to be kept with the ED notes, or with the patient if left at scene. ePR data can be downloaded at the ED for the same purpose, or a printout is left there or with patients left at scene, depending on local system configuration. The original paper forms are then stored and collated centrally. In most services they are scanned, with optical mark data extraction in some, although it can involve manual inputting in other situations. Linkage of information from the paper forms to the computerised call centre information is challenging, although they do share a common identifying field. The ePR enables routine linkage without additional cost or effort – a huge advantage when this is in place.

Protocols and guidelines for paramedics are stored in hard copy only, in various forms – individual sheets of paper, laminated pages, booklets. The ePR brings an opportunity to provide these guidelines and protocols as well as interactive clinical decision support to the scene of care in an integrated format, available at the touch of the practitioner’s fingers.

Despite challenges and setbacks, commitment to ePR implementation remains strong at all levels. It remains national policy to implement an “Ambulance Electronic Patient Record” with a new information standard having been recently published. In this standard, the purpose of the Ambulance Electronic Patient Record is stated as “to improve the comparability and consistency of the information that is recorded by ambulance staff and of the information that is passed to emergency departments and other health care providers by ambulance trusts…. [and] to plan, monitor and improve ambulance services” [22].

**Decision support**

Alternative models rely on the development and implementation of complex interventions. In the case of the SAFER 1 trial, the aim is to avoid unnecessary attendances at Emergency Departments (ED). Implementation involves a number of activities, including training, treatment and referral protocols, and decision support. Decision support tools have been widely introduced into healthcare over recent years, in the UK and internationally. Decision support can be paper based, or computerised, and may be simply guidelines - available in hard copy or electronically, for reference - or tools that need to be completed – paper based forms or more sophisticated interactive software. The intervention tested in the SAFER 1 trial
is an electronic IT intervention which lies at the latter end of this spectrum, and is fully described later in the report (chapter 4).

Additional funding awarded by the National Institute of Social and Health Care Research (NISCHR) in Wales allowed us to carry out a systematic review of the effects of computerised clinical decision support software in the emergency setting on processes and outcomes of care. The draft report of this work is included as appendix 1, as ‘work in progress’. In brief, 20 empirical studies were included in this review [12, 23-41]. Few RCTs of CCDS were identified and all primary research studies of any design were based in ED or Walk in Centres, with none identified from within prehospital emergency care. Findings related mostly to rates of usage and effects on processes of care, with very little information about effects on patient outcomes. Implementation and adoption issues were described qualitatively in some studies, highlighting the need for improved usability and support underpinning implementation.

Overall, the results of the systematic review reinforced the need for the SAFER 1 trial to provide evidence about the clinical and cost effectiveness of CCDS in prehospital emergency care, and about factors which affected implementation within services and adoption by ambulance paramedics.

Rising demand for emergency healthcare, operational pressures

Within the wider context of the modernisation of the NHS, there have been several policy objectives related to emergency healthcare and the management of chronic conditions, which underpin the need for and set up of the SAFER 1 trial [42, 43]. First and foremost has been the pressure on emergency services by seemingly ever-increasing levels of demand and recognition that there is a need to respond to wide range of callers appropriately. Higher demand for emergency care may be related to several factors, including an ageing population with an increasing burden of chronic conditions; problems in accessing primary care; and an increasingly consumerist approach to demand for healthcare [44].

It has been recognised that the current configuration of the NHS and the services it provides is not sustainable [45]. Policy objectives highlight the need to shift services from the acute sector in to the community, and to find ways to reduce the volume of ‘revolving door’ patients – frail patients with multiple clinical and social problems that repeatedly come into hospital though the emergency admission, and are then very difficult to get out of hospital and back to their home environments. Avoidance of emergency admissions has become a key objective for primary, community and emergency healthcare providers.

Objectives for the emergency ambulance service fit within this wider context [6], as expressed in the Bradley report 2009. In order to meet these objectives, a major organisation of English services was undertaken in 2006. Alternative pathways have been developed and implemented in some services, in a piecemeal fashion and, in most cases, without underpinning evidence of safety and effectiveness.

At the same time, however, an even greater emphasis has been placed during this period on operational performance, and changes in the method of measurement of response times created significant pressure to maintain standards of operational performance. National performance standards focus exclusively on measures of response time intervals, for the calls categorised as potentially life-threatening or serious (8 and 14 minutes, respectively). Although there is wide recognition that these performance standards have little clinical relevance, ambulance services have to focus on their achievement, at times to the detriment of all other service initiatives including research.

This policy and practice context at the same time provided the rationale for the study but created challenges for its implementation.

Theoretical underpinning for intervention

The SAFER 1 trial spanned the Medical Research Council phases of development and testing of a complex intervention [46]. A theoretical underpinning for an intervention to be evaluated is a necessary step in the process for developing both the intervention to be tested as well as
the methods for its evaluation. The theoretical basis for CCDS for the emergency prehospital care of older people who have suffered a fall was built on work carried out previously by the research team and other published research in the three areas of:

- Emergency prehospital care – paramedic practice and service delivery
- Care of older people who fall
- Use of computerised clinical decision support for face to face assessment and care

The intervention is hypothesised to work by improving the decision making of paramedics in terms of safe non-conveyance and referral of older people who have had a fall to appropriate community based services. If this can be achieved, based on our best knowledge, we can expect the following beneficial effects [47, 48].

- Better outcomes (fewer subsequent falls and emergency episodes; higher satisfaction with care) for patients, in particular those who would have been left at home with no further care but who are now referred to falls services, but also for those who may have been taken to the ED unnecessarily, with related risks of inpatient admission and hospital related adverse events
- Reduced costs to the NHS and patients due to fewer initial ED episodes, inpatient admissions and subsequent falls and related care
- Improved paramedic skill sets, level of professionalisation and practitioner morale

Uncertainties lie at the following points on the required causal pathway:

1. What is the feasibility of the technical implementation of CCDS in the emergency ambulance setting?
2. Will paramedics use the CCDS?
3. Will they change their current practice in relation to
   a. who to take to ED and who to leave at home
   b. referring patients to the falls service
4. Will introduction of the CCDS lead to improved outcomes for patients?

We designed the SAFER 1 study to gather data about each of these elements of the pathway in order to assess not only outcomes but processes that may lead to improved outcomes.

**Methods**

The lack of completed randomised controlled trials in emergency prehospital care has been acknowledged [49], with increased challenges associated with obtaining consent; the need to follow up patients across multiple providers; and an absence of any research tradition in this sector on which to build methods and compliance to research and treatment protocols.

Research governance requirements, including complex issues related to ethical research recruitment processes, add to the challenges of undertaking trials in the emergency care setting [50].

**Support and Assessment for Fall Emergency Referrals (SAFER) 1: final report format**

This final report provides details of the sixth project commissioned by the DH through the ICTR2 call. With the agreement of the commissioner, we have structured the report so that each chapter forms a stand-alone paper to be submitted to for publication in a scientific peer reviewed journal. Although this results in some repetition across chapters in this way we hope to maximise the dissemination of findings from the trial.
The chapters cover the following aspects of the trial: Methods - trial protocol, as already published (BMC Emergency Medicine); trial implementation - challenges and solutions; clinical effectiveness; cost effectiveness; qualitative findings - patients; paramedics and stakeholder views; discussion and conclusions.

Aspects of the trial that were important but did not fit into the papers defined above are included as appendices. These include: systematic review of effects of CCDS on processes and outcomes of care write up (work in progress); all patient materials; additional analysis charts/tables; site CONSORTs; data flow diagram; description of service user involvement in the trial; systematic review search terms; pilot data collection report and interview guides.
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Chapter 2 Trial Protocol - Support and Assessment for Fall Emergency Referrals. Computerised on-scene decision support for emergency ambulance staff to assess and plan care for older people who have fallen: evaluation of costs and benefits using a pragmatic cluster randomised trial

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The electronic version of this article is the complete one and can be found online at: http://www.biomedcentral.com/1471-227X/10/2

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Abstract

Background

Many emergency ambulance calls are for older people who have fallen. As half of them are left at home, a community-based response may often be more appropriate than hospital attendance. The SAFER 1 trial will assess the costs and benefits of a new healthcare technology - hand-held computers with computerised clinical decision support (CCDS) software - to help paramedics decide who needs hospital attendance, and who can be safely left at home with referral to community falls services.

Methods/Design

Pragmatic cluster randomised trial with a qualitative component. We shall allocate 72 paramedics (‘clusters’) at random between receiving the intervention and a control group delivering care as usual, of whom we expect 60 to complete the trial.

Patients are eligible if they are aged 65 or older, live in the study area but not in residential care, and are attended by a study paramedic following an emergency call for a fall. Seven to 10 days after the index fall we shall offer patients the opportunity to opt out of further follow up.
Continuing participants will receive questionnaires after one and 6 months, and we shall monitor their routine clinical data for 6 months. We shall interview 20 of these patients in depth. We shall conduct focus groups or semi-structured interviews with paramedics and other stakeholders.

The primary outcome is the interval to the first subsequent reported fall (or death). We shall analyse this and other measures of outcome, process and cost by 'intention to treat'. We shall analyse qualitative data thematically.

**Discussion**

Since the SAFER 1 trial received funding in August 2006, implementation has come to terms with ambulance service reorganisation and a new national electronic patient record in England. In response to these hurdles the research team has adapted the research design, including aspects of the intervention, to meet the needs of the ambulance services.

In conclusion this complex emergency care trial will provide rigorous evidence on the clinical and cost effectiveness of CCDS for paramedics in the care of older people who have fallen.

**Background**

Demand for immediate care through the emergency ambulance service is increasing across the UK and internationally. However up to half of all callers have no clinical need for an emergency department (ED). This includes many older people who have fallen. Though health policy in the UK encourages ambulance services to offer alternative services to such callers, there is little evidence about the safety and effectiveness of new models of care. Alongside training and referral pathways, handheld devices with decision support software could improve the care of this vulnerable patient group.

Falls in older people are recognised internationally as an important issue [1,2], with high human and organisational costs. Reduction in quality of life and physical activity lead to social isolation and functional deterioration, with a high risk of dependency and institutionalisation [3-5]. In the UK, falls account for 3% of total National Health Service (NHS) expenditure [6], and the prevention of falls in older people is a priority [7,8]. Most people who fall do not seek medical advice [9,10] but older people still account for between 12 and 21% of ED visits. Although prevention strategies are effective [8], reduction of falls, injuries and associated morbidity depend on early identification of people at high risk and delivery of interventions across traditional service boundaries [11]. This is reflected in current national and international guidelines [12-14].

In London older people who fall and call 999 for an emergency ambulance response, account for about 60,000 attendances each year or 8% of all emergency ambulance responses [15]. This is similar to the 7.5% of the emergency workload attributable to falls in an urban Emergency Medical Service (EMS) system in the US [16]. Non-conveyance to the ED is high in this group - about 40% in London [15], elsewhere in the UK [17,18] and in the US [16]. Most, (90%), of the falls ambulance staff attend but do not convey to the ED occur in the home [19]. Non-conveyance of patients attended by emergency ambulances is recognised internationally as a safety and litigation risk [20]. Most UK ambulance services have guidelines suggesting that all patients be conveyed to the ED unless the patient refuses to travel to
hospital. In practice, however, informal triage by ambulance staff to decide who can be safely left at home has been generally accepted by ambulance services across the UK. However there is no established referral pathway, or requirement to inform, for example, the patient's General Practitioner (GP) about any emergency ambulance call. Little is known about how, in the absence of specific protocols or training to leave older fallers at home, ambulance staff make these decisions. However a US-based study recognised the pragmatic nature of the process of negotiation with the patient about whether to go to hospital [21]. In the UK, qualitative studies have found that crew members deciding whether to take patients to the ED, base decisions on 'intuition' and distance to receiving unit [22-24]. Unfortunately the use of intuition in clinical decision-making is generally considered a source of error and bias [25].

A recent systematic review of the effectiveness of multi-factorial assessment and targeted intervention for falls injury prevention in community and emergency settings concluded that there have been "few large-scale, high-quality randomised trials. Studies are needed that have the power to detect important effects on the number of fall-related injuries and quality of life, so as to resolve uncertainty about the clinical and cost effectiveness" [26] of falls interventions.

This trial addresses an important area of care for older people who fall. It combines a technological innovation with a new model of service delivery across provider boundaries. Evaluation of the costs and benefits of this complex technology will provide valuable information about the development of appropriate care pathways and the potential avoidance of hospital admissions in this vulnerable patient group.

**Methods/Design**

**Study Aim**

The aim of this research is to assess the costs and benefits of a complex healthcare intervention for older people for whom an emergency ambulance call has been made following a fall. The intervention comprises CCDS software and training for paramedics to help them decide whom to take to hospital and whom to leave at home with referral to a community-based falls service.

**Study Design and Setting**

The study is a pragmatic cluster randomised trial with a qualitative component. Allocation will randomise paramedics rather than patients, since the intervention targets health professionals with the aim of studying effects on patient outcomes [27].

**Intervention**

The intervention being evaluated is a complex package which comprises paramedic training and CCDS software. The software is installed onto hand-held computers, forming part of an electronic patient record (EPR).

We shall evaluate this package as a whole, in line with the recommendations of the Medical Research Council (MRC) for evaluating complex interventions to improve health [28], as the component parts are interdependent and not easily separated for the purpose of testing.
Paramedics randomly allocated to the intervention group will receive a one-day classroom-based training course. Training will include systematic demonstration of the mechanics and functionality of the software, coupled with practice and supervised role play. Critical reflection and discussion will be encouraged throughout the training. Knowledge reviews will ensure competence and understanding of key aspects of the software functionality. Paramedics will then have a period of four weeks to practise using the new technology. Towards the end of this period, we shall audit their use of the CCDS to ensure they have achieved proficiency.

The CCDS software is on a hand-held tablet Personal Computer (PC), for use by ambulance paramedics attending patients. It will help them to make decisions about the clinical and social care needs of older people who fall. The CCDS software sits alongside the EPR. The CCDS prompts the assessment and examination of injuries associated with the fall, co-morbidity that may have contributed to the fall (e.g. breathlessness or chest pain), psycho-social needs (e.g. cognitive state and ability to undertake activities of daily living) and assessment of environmental risk. Based on these assessments, the CCDS suggests a care plan (e.g. transfer to ED, referral to specific community services and/or patient advice). The clinical assessment component of the CCDS was the intervention in a previous trial with ambulance services [29].

**Control intervention**

Patients eligible for inclusion in the trial but attended by control paramedics will receive usual emergency ambulance service care at each study site. This comprises a paper-based decision support system in the form of a structured questionnaire at each site.

**Outcomes**

**Primary**
- Interval to the first 999 call or ED attendance categorised as fall; or death

**Principal**
- Interval to the first subsequent 999 call, ED attendance or death (event free period)
- Quality-adjusted event free period

**Secondary**
- Number per patient of further falls for which a 999 call is made
- Number per patient of further 999 calls
- Number per patient of self-reported further falls
- Number per patient of ED attendances
- Number per patient of emergency hospital admissions
- Number per patient of GP (General Practitioner) contacts
- Mortality rate
- Health related quality of life
- Patient satisfaction
- Fall-related self-efficacy (fear of falling)
- Change in place of residence
- Length of hospital stay
- NHS costs
- Personal costs to patient and family
• Pathways of care: proportions of index falls:
  ◦ conveyed to ED
  ◦ referred to falls service
  ◦ referred to GP
  ◦ left at scene without further care
• Operational indicators: length of time:
  ◦ spent on scene
  ◦ in ambulance service job cycle
  ◦ in episode of care
  ◦ to respond to 999 call (effect of intervention on response time?)
  ◦ for falls service to respond
• Quality of care: compliance by paramedics with:
  ◦ ambulance service treatment protocols
  ◦ decision support algorithms
  ◦ clinical documentation
  ◦ protocol for referral to falls service

These outcomes are consistent with those recommended in recent guidance from the PRvention Of FAIlss Network Europe (PROFANE) [30].

Participants
The trial will be carried out in three ambulance services. In each service we shall recruit paramedics from ambulance stations that serve a General Hospital with a full ED and one or more community-based falls services.

Paramedic recruitment and consent
Paramedics are eligible for the trial if they are on active duty at ambulance stations within its catchment area. We shall write to eligible paramedics to invite them to participate. We shall select 24 volunteers from each service at random and allocate half to intervention group and half to controls, again at random. Of these 24 we expect 20 to complete patient recruitment and four to withdraw.

Patient recruitment and consent
Patients are eligible for the trial if they are:

• aged 65 or over
• the subject of an emergency ambulance call categorised by the call-taker as a fall
• without priority symptoms
• attended by a trial paramedic during the recruitment period
• living in the catchment area of a falls service; and
• not living in residential care

To make findings apply to all such patients, we shall not exclude patients with other co-morbidities, including cognitive impairment. However we shall recruit them to the trial only once, namely the first time they meet the inclusion criteria within the study period.

As most emergency callers are distressed and in urgent need, we shall not seek consent by phone or at first attendance. Instead, we shall identify them from routine ambulance service information gathered during the 999 call. Authorised staff from participating services will write to them 7 to 10 days after their falls to tell them about the study and ask them to ‘opt out’ if they do not wish the trial to contact them again or to access their medical data. They will then give the research team details of patients who do not opt-out for study follow-up.
**Data collection methods**

Participating patients will receive questionnaires one and six months after their index fall. Where necessary, we shall administer these through interviews. Questionnaires will measure health-related quality of life through the SF12v2 [31], fear of falling through the Modified Falls Efficacy Scale [32], and self-reported falls. At one month they will estimate patient satisfaction with the Quality of Care Monitor [33]. We shall track patients through the emergency ambulance system, ED departments, GPs and coroners to identify further contacts with these services (or death) within six months. We shall collect diagnostic codes for each contact.

We shall derive time spent on scene (interval between time of arrival of ambulance at patient and leaving the scene of the call), per job cycle (interval between 999 call and completion of call) and per episode (interval between 999 call and completion of care - including time at ED) from routine ambulance and ED records for all calls meeting the study inclusion criteria. We shall assess completeness of clinical documentation relevant to the care of older people who fall from Patient Clinical Records and EPRs completed by paramedics. We shall assess compliance with treatment and referral protocols from ambulance service and falls service records.

In each ambulance service we shall sample 10 older people who fall and are attended by ambulance crews using the new technology. Trial researchers will interview them in depth, using a semi-structured interview schedule to ascertain their views and preferences about the service they received.

We shall also conduct semi-structured interviews or focus groups with intervention group paramedics before and after implementation of the CCDS technology, and with other stakeholders, notably in the falls services. Interview schedules and topic guides will cover: views about the emergency care of older people who fall; the process of decision-making and triage; and issues in implementing the new software. We shall record and transcribe interviews and discussions.

**Follow-up**

The research team will work with each participating ambulance service to track patients who meet the inclusion criteria and who have not opted out. They will also liaise with Patient Affairs Managers (or equivalent) at local hospitals and coroners every week to check that these patients have not died. In this way we seek to avoid contacting patients who have recently died.

**Patient involvement**

Through two Clinical Research Collaboration Cymru networks - TRUST (Thematic Research network for emergency and UnScheduled Treatment) [34] and Involving People - we have recruited two user representatives to the SAFER 1 Trial. Their role is to attend team meetings and advise on all aspects of the trial, especially where there is contact with patients. In particular they provide feedback on the acceptability of trial questionnaires and patient information. We shall also convene a panel of users to provide more general advice throughout the trial.

**Health economics**

We know little about the cost effectiveness of alternative response interventions in emergency ambulance care [35-40]. Therefore economic analysis will estimate the costs of providing the new intervention, the consequences of the scheme for the wider health service (e.g. ED attendances and inpatient admissions) and the costs to patients and families. We shall collect data on the use of health service resources by each patient from paramedic records, GP
records, routine hospital records and patient-completed questionnaires. We shall estimate costs by multiplying resource use by unit costs estimated through a micro-costing study within the trial. We shall use the SF6D, derived from the SF12, to estimate the quality-adjusted life years (QALYs) gained from the intervention and economic modelling to estimate the incremental cost-per-QALY. We shall present these ratios with their associated cost-effectiveness acceptability curves. We shall undertake sensitivity analysis to assess the robustness of the results to plausible changes in the configuration of the scheme and other healthcare activity.

**Ethical considerations**

The Multi-Centre Research Ethics Committee for Wales has given full ethical approval for the study (08/MREC09/12), including tracking patients across service providers. Although consent mechanisms based on opting out are unusual, two recent studies have received ethical approval to use this mechanism as the only feasible way to include patients in this vulnerable and hard-to-reach group, and thus improve their care [41,42].

To monitor the progress of the trial we have established two independent bodies - Trial Steering Committee (TSC) and Data Monitoring & Ethics Committee (DMEC). The DMEC, with a Clinical Trials Unit Director as chair and members from the fields of geriatrics, public health and statistics together with a user representative, reports to the TSC. The TSC is chaired by a primary care academic and includes members from an ambulance service and emergency medicine, and another user representative.

**Sample size**

We designed the trial to detect clinically important changes in the primary outcome - the time to first subsequent reported fall (or death). We judged that we could recruit 20 active paramedics (ten in intervention group, and ten in control group) at each site. As there is no published data on the distribution of time to first reported fall, we estimated the sample size conservatively, using the rate of subsequent falls (or deaths).

From data from participating ambulance services, we expect 250 older people to fall in each site each month. However it will not be possible to identify all who have fallen as eligible for the trial from information given during the emergency call. Furthermore some patients will opt out. Estimating conservatively that we can recruit 133 older people per site per month, a recruitment period of four months will enable us to recruit 500 patients per site, that is 25 per cluster and 1500 in all.

This sample size will yield 80% power when using a 5% significance level to detect a fall in the proportion of participants who make another emergency call for a fall (or death) within six months from 50%, as found in London recently [41], to 40% if, as we expect, the intra-cluster correlation coefficient is less than 0.035. Since this proportion is a binary variable, the time to first reported fall (or death), which is an interval variable, will yield greater power. We shall also have power to detect an effect size of 0.20 (i.e. one fifth of the population standard deviation) in SF12 scores.

**Randomisation and blinding**

The ‘West Wales Organisation for Randomised Trials in health and social care’ (WWORTH) is randomising paramedics between intervention and control. We shall conceal the resulting allocation until we reveal it by inviting individual paramedics to training days. Blinding participants to trial group allocation is neither feasible nor appropriate in a pragmatic trial like this.
Older people who fall and are attended by a control paramedic will receive the participating ambulance service's standard care. As it may not be feasible to blind the dispatchers in ambulance control to the trial group of their paramedics, we shall monitor and, if necessary, manage ambulance dispatch to avoid selection bias, which might manifest itself in a higher transfer or recruitment rate in the intervention group.

**Statistical methods**

We shall comply with all standards defined in the CONSORT guidelines [43]. We shall compare measures of process, outcome and cost between intervention and control patients by 'intention to treat'. As we expect many subsequent emergency calls for falls, many participants will call more than once during the trial period. If the intervention is effective, therefore, later attendances by paramedics with the CCDS could dilute the true effect on outcomes. For primary analysis, nevertheless, participants will remain in the group to which they are allocated.

We shall compare our primary and principal outcomes between groups by multi-level survival analysis. This will include separate analyses for later falls (including deaths) and for deaths alone. We shall review all deaths within 72 hours, the typical interval between index fall and referral to falls service. We shall monitor all deaths within the follow-up period of 6 months according to the WWORTH Standard Operating Procedure for Safety Monitoring. We shall compare secondary outcomes between groups using parametric or non-parametric methods as appropriate.

The trial statistician undertaking analyses will be blind to the trial group of all participants. We shall analyse qualitative data thematically using content analysis.

**Discussion**

**Strengths**

There have been "few large-scale, high-quality randomised controlled trials of the effectiveness of multi-factorial assessment and targeted intervention to prevent falls in community and emergency settings" [26]. Studies are needed that have the power to detect important effects on the number of falls and quality of life, and resolve uncertainty about the clinical and cost effectiveness of falls interventions. This trial responds to this call by evaluating a potentially powerful combination of technological innovation and a new model of service delivery.

**Weaknesses**

Since the SAFER 1 trial received funding in August 2006, several issues have delayed implementation, including:

• Radical ambulance service reorganisation took place in England in 2007, with 29 ambulance services reduced through mergers to 12 regional Ambulance Service Trusts.

• Senior staff at each of the participating services changed, including Chief Executive and Director of Information. As a result, the research team has had to renegotiate participation at a time when research was not an organisational priority in England or Wales.

• The national ‘Connecting for Health’ (CfH) programme [44] introduced the EPR programme into participating ambulance services alongside the SAFER 1 project. Although we explored opportunities for collaborating with CfH EPR software providers, timetables were not compatible and two of the original three ambulance services withdrew from the trial.
Although many ambulance services expressed interest in the SAFER 1 trial, these challenges prevented them from participating. Both of the English ambulance services originally recruited to take part in the study had to withdraw, together with a third English service that was keen to participate.

**Progress**

Fortunately two more English services have recently agreed to participate, and are preparing for the trial. In Wales, where there are no immediate plans to introduce EPR, implementation is underway (Figure 1). Paramedics have been recruited, randomised and trained, the falls pathway has been negotiated, and research governance processes are complete. Study hardware, including computers, docking stations, printers and servers, has been fitted into 13 vehicles in Swansea. We have also negotiated data capture for the trial with security levels acceptable to all parties to the trial in Wales.

**Figure 1: CONSORT diagram for the South Wales site.**

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Cluster unit = paramedic
Assessed for eligibility = 47

Excluded = 25
- Not on active duty
- Not meeting inclusion criteria
- Refused to participate

Randomised = 24

Participants allocated to intervention = 12
Participants allocated to standard treatment = 12

Paramedics delivered intervention = ?
Paramedics delivered standard care = ?

Reasons:
Participants did not deliver intervention = 7
Participants did not deliver standard care = 7

Reasons:
Participants received intervention =
Participants received standard treatment =

Participants did not receive intervention =
Participants did not receive standard treatment =

Reasons:

Paramedics lost to follow up =
Participants lost to follow up =

Reasons:
Unable to trace
Opt-out form returned
1 month questionnaire not returned
6 month questionnaire not returned
Deceased

Participants analysed =

(average cluster size, range of cluster sizes)

Participants excluded from analysis =

Reasons:
Unable to track electronically

Participants analysed =

(average cluster size, range of cluster sizes)

Participants excluded from analysis =

Reasons:
Unable to track electronically
Conclusion

This is a trial of a complex intervention in a challenging setting. Evaluation of this intervention is essential to underpin future purchasing and service development decisions, at both national and local levels. We aim to provide rigorous evidence that will be useful to practitioners, managers and policy makers on the clinical and cost effectiveness of computerised clinical decision support for paramedics caring for older people who have fallen.

Competing interests

JD is shareholder in, and clinical director of, Plain Healthcare who supply the CCDS software used in the trial. He will play no part in data management or analysis.

Authors' contributions

HS and JD formulated the research question and conceived the study. All co-authors helped to develop the funded protocol. BW, SG, IH, JP and AS have since refined that protocol. All authors critically reviewed and approved the final manuscript.
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Chapter 3 After the fall: organisational difficulties of setting up an RCT in emergency care

Abstract

Conducting randomised controlled trials (RCTs) in health services research can be complex and difficult. This is especially the case in pre-hospital emergency care where implementation, randomisation and recruitment in a high pressure clinical environment presents particular challenges. However, it remains the case that a better evidence base is needed to support good clinical practice in the pre-hospital care. We have used our experiences of conducting a RCT of a pre-hospital computerised falls assessment and referral system to describe the challenges and solutions encountered. We have used a qualitative approach using research proposals and reports, research diaries and meeting minutes to describe the process of trial implementation in 2 UK ambulance services.

The main challenges were development of a complex intervention, recruitment and retention of study sites, implementation of the intervention and data collection and management processes. A number of key policy changes, including national restructuring of the ambulance service in England before the trial commenced affected all of these issues. The conflicts between maintaining operational performance and conducting research within an ambulance service, the complex relationships between multiple stakeholders, impact of external events and engaging management support led to significant delays in trial implementation. Study costs also escalated.

Factors which helped resolve problems included developing project management strategies to tackle specific issues, engaging ambulance service paramedics in protocol development and data capture and funding designated ambulance service personnel to link study services and the research team. The experience has shown that it is possible to conduct RCTs in the pre-hospital setting but in future the processes involved can be improved by continued development of research capacity within ambulance services and aligning research activity with strategic priorities and service objectives.
Introduction

Much has been written about the difficulties of conducting RCTs, both in general [1,2] and more specifically around recruitment and engagement both in primary [3-5] and mixed care settings [6-8]. Less is known about specific issues within pre-hospital emergency care. Reasons for the paucity of RCTs in the emergency pre-hospital care setting include methodological difficulties related to consent, randomisation and implementation, a historical focus on operational priorities and the relatively recent professionalization of paramedics and consequent shift towards evidence based care [9-11]. Internationally, the lack of scientific support for many pre-hospital interventions and need to create an evidence base of credible and convincing research studies, including RCTs, to support good clinical practice is well recognized [12-14]. However, without a greater understanding of the processes involved in the establishment and implementation of trials in this complex and rapidly changing clinical environment, this task is extremely challenging.

We have used the experiences involved in setting up a pre-hospital RCT - The SAFER (Support and Assessment for Fall Emergency Referrals) 1 trial – to provide a narrative report of the challenges encountered, the impact on delivery of the trial and the solutions to these challenges that provides generate valuable lessons to inform future trials’ design. The aims of the paper are to:

- Describe the challenges in conducting a RCT of a complex intervention in emergency pre-hospital care related to:
  - Recruitment and retention of collaborating sites
  - Development and implementation of the health technology to be evaluated
  - Set up and implementation of trial design and data collection processes
- Organisational and technical factors
- And to discuss how to overcome the challenges listed above

The SAFER 1 Trial

Ambulance services are struggling to cope with steadily increasing demand. In the UK the number of 999 calls to ambulance services increased by 9% over the 2 year period 2008-2010 [15]. Research evidence has shown that the traditional response of a lights and sirens ambulance and transportation to an Emergency Department (ED) does not match with the needs of many 999 callers [16]. A key objective of strategic plans set out for Emergency Medical Services (EMS) in England, the USA and Canada is the development of flexible responses to a wide range of conditions in collaboration with a range of healthcare providers [17-19], although there is limited evidence about the safety or effectiveness of new models of care [10]. Internationally, a significant proportion of emergency ambulance calls are made for older people who have fallen [20, 21] and this is one group for whom a community based alternative may be more appropriate. These patients have a high risk of repeat falls, injury, loss of independence and quality of life and death [22-24]. A falls service intervention targeted at ED attenders designed to address these issues has been shown to be effective [25], as has assessment and referral in the community of older people following a 999 call by paramedics with extended training [26]. It has been suggested that early referral to a falls service by paramedics at the incident scene, so that individuals can remain at home rather than be transported to an ED, could be one way to improve care for this vulnerable patient group. The SAFER 1 trial has been designed to assess the costs and benefits of this new model of care with Computerised Clinical Decision Support (CCDS) as the core intervention. It was funded by a UK Department of Health research programme to develop the role of technology in supporting chronic disease management, self-care and healthy living.
### Table 1: Key features of the SAFER 1 trial, as funded

| **Aim** | To assess the costs and benefits of hand-held computerised clinical decision support (CCDS) technology for the on-scene assessment and care of older people who fall and call 999 |
| **Intervention** | Tablet computer with CCDS to be used by paramedics to help them reach a decision about whether a patient who has fallen needs to travel immediately to hospital or can be referred to a community based falls service |
| **Design** | 1. Cluster randomised trial – 20 paramedics in each of 3 ambulance services randomly allocated to intervention or control (standard current care) group. Comparison of outcomes in intervention and control groups at 1 and 6 months  
2. Qualitative study with NHS staff to explore practical service and implementation issues  
3. Economic evaluation to assess cost-effectiveness |
| **Study Sites** | Three ambulance services  
A national (Welsh) UK service (AS1)  
A predominantly rural English County service (AS2)  
A mixed urban and rural English County service (AS3) |
| **Outcome measures** | Number of further falls resulting in a 999 call, ED attendances, hospital admissions or death; and period until the first one of these  
Quality of life, independence and satisfaction of patients and carers  
Operational processes – on scene time, job cycle time  
NHS resource utilisation |
| **Duration** | 30 months August 2006 – January 2009 with 1 year patient recruitment period in 2007 |

The planned evaluation was designed using the principles set out in the MRC framework for evaluating complex interventions (Box 1).

**Box 1: MRC principles for evaluation of complex interventions**

> Developing, piloting, evaluating, reporting and implementing a complex intervention can be a lengthy process. All of the stages are important, and too strong a focus on the main evaluation, to the neglect of adequate development and piloting work, or proper consideration of the practical issues of implementation, will result in weaker interventions, that are harder to evaluate, less likely to be implemented and less likely to be worth implementing.
The mixed methods approach of a randomised trial to assess clinical effectiveness, economic evaluation to assess cost-effectiveness and qualitative study to explore practical issues of implementation into clinical practice was adopted. This design was used so that the evaluation could provide the evidence needed by ambulance services, community based services and health care commissioners to make informed decisions about future use of this new model of service delivery.

The SAFER 1 trial had to seek extensions on 3 occasions, the latest until 2011. The original planned start of the evaluation was pre-empted by the announcement of major NHS policy changes and initiatives, significantly the National Programme for IT (NPfIT), and service reorganisations at both local and national levels. These occurred after funding had been awarded and ethics approval gained and resulted in significant modifications of the project timescales and service intervention. They also increased the complexities of the inter-and intra-organisational co-ordination and collaboration needed to move the evaluation forward and coincided with changes in the processes of obtaining R&D and information governance permissions. These events and the solutions needed to enable the trial to eventually take place are the focus of this paper.

Methods

This paper emerged as a useful output for learning from the study due to difficulties encountered during the trial. It was not pre-planned but opportunistic. Data available for analysis were therefore not designed and collected according to predefined questions but were collated from routine trial design findings, reporting and management sources.

Data sources

Two broad areas of data were used:

- Trial events data: telling the story of the trial set up
- Trial explanatory data: related to challenges, conduct, communication and perceptions of key players of RCT implementation providing understanding of the causes of events

Trial events data were extracted from the following sources: original project proposal, funding application, meeting minutes, reports to the funder, and letters sent from partner organisations. These set out the original timelines, provided factual evidence of the policy changes and external events affecting the project and consequent revised timelines.

Trial explanatory data were extracted from meeting minutes, action logs, a data collection pilot report, detailed research protocols and progress reports to the funder. Project task and status sheets were also used and a project management action log was available for the period May 2009-November 2010 which recorded technical and non-technical action points at one site. Two reflective research diaries kept by researchers described participant observations of group and individual meetings. Emails sent and received by the research staff from key players were also used.

Analysis

Basic qualitative descriptive analysis [27,28] of trial event data was used to give a comprehensive summary of the events that took place from the initial agreement of funding to recruitment of the first patients into the trial. Trial explanatory data were analysed thematically using content analysis [29-31] using the framework set out in the objectives, that is recruitment and retention of study sites; development of the intervention technology and implementation of trial design and data collection processes. A comparative analysis of reports to the funders, researchers’ meeting minutes, action logs, management action logs and the data collection pilot report was undertaken to identify recurrent themes within each item. These analyses were performed independently by two separate researchers to allow comparison between their workings and periodically referred to a broader group of researchers involved in the trial to check for reliability.
Results

Trial events

The descriptive qualitative analysis has been used to produce this narrative on the main events that impacted on the progress of the trial.

The funding for the trial was agreed at the end of 2005 and available to enable the project to start in August 2006. Patient recruitment was planned during 2007 and the final follow up and reporting to be completed by January 2009. Ultimately patient recruitment did not begin until November 2009, 2 years and 9 months from the planned start date and 9 months after the original study end date. Figure 1 gives a summary of the original trial timetable and the actual time for each component.

Figure 1: Gantt Chart Comparison – planned versus actual activities

In the intervening period between the funding decision and the start of the study a number of significant key policy changes relevant to pre-hospital care within the UK NHS were implemented. These were some of the recommendations of the 2005 policy document “Taking Healthcare to the Patient –Transforming NHS Ambulance Services” [17] and the NHS National Programme for Information Technology (NPfIT). These events were unanticipated when the study was being designed but had a significant impact on progress.

The changes having the biggest impact on the delivery of SAFER 1 are summarised in Table 2
Table 2: The changes having the biggest impact on the delivery of SAFER 1

<table>
<thead>
<tr>
<th>Policy change</th>
<th>Ambulance Service Impact</th>
<th>Study Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Taking Healthcare to the Patient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Standardisation of the call start time for reporting response time performance to when the call is connected to the ambulance control room (Call Connect). Previously call start time was when a chief complaint is identified leading to variation between services in clock start time and hence reported response time performance.</td>
<td>From April 2007 all English ambulance services must report response time performance measures (75% of category A calls within 8 minutes and 95% of category B calls within 19 minutes) using the new start time. Operational pressures to improve response time performance. Management pressures to achieve response time performance targets. Central pressure from Performance Improvement Teams.</td>
<td>Response time performance was the primary focus for ambulance services. Less commitment to research, providing appropriate staff to implement the trial and the reason given for withdrawal of some study sites.</td>
</tr>
<tr>
<td><strong>Taking Healthcare to the Patient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Improving strategic capacity by increasing the size of ambulance services to attract high calibre managers and lead transformation.</td>
<td>Following a consultation the number of ambulance services in England was reduced from 31 to 12 in 2006. The resultant mergers required a period of significant restructuring of operations and management teams both in the lead up and subsequent establishment of the new regional organisations.</td>
<td>Two original sites became part of new regional ambulance services. Loss of continuity with key personnel changes. Re-negotiation of participation as new business processes for managing R&amp;D introduced.</td>
</tr>
<tr>
<td><strong>National Programme for Information Technology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. An NHS initiative managed by the NHS Connecting for Health (CfH) information team to introduce a National Information Technology infrastructure including a single electronic patient record that can be shared by different service providers. The initiative began in 2005 as a central system, moved to more local development by the 12 Strategic Health Authorities in 2007 and was abandoned as a national initiative with all further development devolved in 2010.</td>
<td>One feature of the single electronic patient record was the development of an electronic patient report form (ePRF) for use by ambulance services using tablet handheld computers. This is to allow pre-hospital information to be permanently recorded for each patient attended within their patient record and shared with other healthcare providers. Some ambulance services had already been exploring this but NPfIT made the ePRF part of a national initiative with national rollout using specified ePRF providers. Renegotiation with trial clinical decision support software and ePRF providers to enable the intervention to be implemented. Recruitment of new study sites to fit with the intervention development timescales. Additional testing and work to set up and agree data collection and security processes.</td>
<td></td>
</tr>
<tr>
<td><strong>4. Introduction of new ethics, research and information governance processes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Big change for all NHS services but particularly so for ASs who didn’t have a research tradition so this was new – risk averse and progress was slow in getting to grips with the complex new processes.</td>
<td>Delays in gaining necessary research and information governance approvals.</td>
</tr>
</tbody>
</table>
Development and implementation of the health technology to be evaluated

The original study proposal was to evaluate the CCDS software embedded within a simple electronic Patient Report Form (ePRF) developed by one software company (S1). The subsequent national plan to roll out an ePRF across English ambulance services made this impractical. The study team therefore began negotiations with the two software companies that had successfully tendered to deliver the ePRF in England – S2 (covering the ‘Southern cluster of services) and S3 (covering the ‘Northern Cluster’). Only S2 could work within the study timescales but both of the two existing English study sites (AS2, AS3) were in areas outside the southern cluster so the SAFER 1 trial could not continue in these locations.

The team made new contacts in ambulance services within the Southern cluster, as well as facilitating negotiations between S2 (the ePRF provider) and S1 (the CCDS provider) concerning the CCDS hardware and software requirements for integration with the ePRF and. AS1 was unaffected by the national plan in England and agreed to participate in the trial using the S1/S2 solution. During 2007 a new ambulance service was recruited (AS4) and the research team worked with AS4 for one year to set up the trial, but in 2008 this service decided to withdraw because of operational pressures. By this time the national IT programme was delayed and some activities devolved locally allowing ambulance services to proceed with their own plans.

The ambulance services in England that had made the most progress with implementation of the ePRF were using the software developed by S3 in the northern cluster and therefore negotiations were reopened with S3 and work towards integration of the S3 ePRF and S1 CCDS agreed. Two new study sites were recruited early in 2009, (AS5 and AS3 – one of the original study sites who had withdrawn when the early ePRF solution was with the alternative supplier). AS5 quickly approved the project and trial set up began. AS3 worked with the research team for over six months before performance pressures, as well as concerns about IT capability and consenting procedures led to their withdrawal in August 2009. The consequence of these complex negotiations was that when the trial finally began in 2009 there was no single solution to the planned intervention and instead two different models emerged:

AS1 – The CCDS software developed by S1 to be used alongside an ePRF developed by S2
AS5 – The CCDS software developed by S1 to be used alongside an ePRF developed by S3

The main consequence of these events was that the requirement to embed the CCDS in two ePRF systems was not envisaged in the original study design, and it was unclear who would bear the costs of this IT integration. The research team and the study ambulance services lacked the funds for this and the ePRF developers had little incentive to prioritise allocation of resources to this work. As a result, the two versions eventually used were substantially different in design and workflow to the original design described in the funding application with consequent uncertainty about the usability of the final systems (Table 3).
Table 3: Features of intervention software and hardware in final participant sites

<table>
<thead>
<tr>
<th>Feature</th>
<th>AS1 (Site 1)</th>
<th>AS5 (Site 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCDS software</td>
<td>• Plain Healthcare CCDS software (S1)</td>
<td>• Plain Healthcare CCDS software (S1)</td>
</tr>
<tr>
<td></td>
<td>• Linked to and accessed via ePRF software</td>
<td>• Standalone software</td>
</tr>
<tr>
<td></td>
<td>• CCDS package accessed online</td>
<td>• CCDS package installed on tablet computers</td>
</tr>
<tr>
<td>ePRF software</td>
<td>• Ortivus ePRF (S2)</td>
<td>• Medusa Siren ePRF (S3)</td>
</tr>
<tr>
<td></td>
<td>• Installed on tablet computers</td>
<td>• Installed on tablet computers</td>
</tr>
<tr>
<td>Computers</td>
<td>• Toughbook ruggedized tablet computers</td>
<td>• Toughbook ruggedized tablet computers</td>
</tr>
<tr>
<td>Printers Chargers</td>
<td>• In cars and ambulances</td>
<td>• In ambulances</td>
</tr>
<tr>
<td></td>
<td>• In car chargers and docking stations in ambulances</td>
<td>• In car chargers and docking stations in ambulances</td>
</tr>
<tr>
<td>Data Storage</td>
<td>• Data transmitted via GPRS to NHS servers managed by Health Solutions Wales</td>
<td>• CCDS output printed out by paramedics or stored as electronic files on tablets for downloading at AS</td>
</tr>
</tbody>
</table>

Recruitment and retention of collaborating sites

Development of the intervention technology resulted in several changes in study sites over the 3 year period 2006-2009. However this was not the only factor influencing recruitment and retention of collaborating sites. The Ambulance Service reorganisation in England in 2006 meant that 2 of the original ambulance sites (AS2&3) effectively ceased to exist. Although initially these services remained committed to participating in SAFER 1, the reorganisations resulted in new management arrangements and uncertainty for some staff about the future of their jobs. A phase of renegotiation with senior managers at each of the new ambulance services was required before the issues around development of the intervention forced their withdrawal.

The impact of the national restructuring of ambulance services in England did not involve AS1, however the trial start was delayed in this service while the issues around intervention development were being resolved and during this time there was significant restructuring in AS1 with changes in key personnel, including one year when five Chief Executives were in place. Internal structures and processes changed significantly and during 2007 the research team were asked to prepare a new business case to present to the Trust Board for approval through newly introduced processes.

The impact of standardising the start time for response time performance produced significant operational pressures for ambulance services as they attempted to implement this change and maintain response time performance targets [32]. At the same time the organizational changes and period of instability created by the mergers of ambulance services during reorganization together meant that, not surprisingly, during this time ambulance service focus was directed at stabilizing these new organisations and achievement of performance targets. AS4 was recruited to replace AS2 & AS3 but withdrew from the SAFER 1 due to pressures on operational performance and changes in leadership. Similarly, AS3 who initially withdrew because of the intervention developments but later rejoined the trial, finally withdrew citing operational pressures on response time target achievement as the main reason. The start of the trial in AS1 was delayed on several occasions, partly due to severe performance pressures but also because the research team were attempting to co-ordinate the start with new services recruited to the study.

Set up and implementation of trial design and data collection processes

An important component of any trial is gaining the necessary ethical and research governance approvals. An initial application for ethics approval was made in April 2006 however approval requires finalisation of study sites and timetable. New systems for gaining R&D permissions and changes to information governance processes were introduced during this time. This
increased the administrative burden and held up progress as potential participating sites familiarised themselves with the revised processes and re-assessed associated risks. The delays resulting from changes to the intervention and recruitment of sites and compliance with new permissions processes meant that final ethical approval was not gained until July 2008.

The external factors described above had a significant impact on both the development of the intervention and recruitment of sites. Once these difficulties had been overcome the implementation of the trial and agreement on processes for collecting information on recruited patients in an operational setting was dependant on the co-operation and involvement of the study services. The thematic analysis has revealed a number of key internal factors that influenced trial implementation that can be summarised as 3 main themes. Figure 2 gives a selection of illustrative quotes related to these themes

**Theme 1 - Management leadership and direction**

Strong leadership at the senior level could have created a climate in which middle managers were encouraged to participate fully in the trial. When senior managers did encourage middle managers to work with the research team they were a catalyst for rapid change. However, the explicitly hierarchical structure of the decision-making processes meant that senior level support was essential to the project’s success but this resulted in delays and at times halted the project’s progress entirely. The number of multiple stakeholders with different values, priorities and ways of working accounted for much of the challenges and friction encountered. The range of stakeholders is illustrated in box 2.

**Box 2: Stakeholders involved in the SAFER 1 trial**

<table>
<thead>
<tr>
<th>Stakeholder Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>University academic units</td>
<td>4</td>
</tr>
<tr>
<td>Study sites (2 finally involved in trial completion)</td>
<td></td>
</tr>
<tr>
<td>including senior management, operations, R&amp;D, training,</td>
<td></td>
</tr>
<tr>
<td>paramedics</td>
<td></td>
</tr>
<tr>
<td>Software developers (3)</td>
<td></td>
</tr>
<tr>
<td>Falls service (2)</td>
<td></td>
</tr>
<tr>
<td>Age UK</td>
<td></td>
</tr>
<tr>
<td>Public &amp; patient involvement group (1)</td>
<td></td>
</tr>
</tbody>
</table>

One ambulance service (AS1) adopted the PRINCE 2 approach to project management and although there were delays in gaining funding, and hence assigning suitable project management personnel this was an effective solution to solving some problems. Nevertheless the complexity of technical issues limited the impact of the PRINCE 2 change approach.

**Theme 2 - Inter and intra-organisational collaboration involving information sharing and IT solutions**

For the participating ambulance services, it was important to ensure that clinical audit and information governance standards of data storage, protection, retrieval and transfer were maintained in the move from paper to electronic records. Creating firewalls for the purposes of the research study and testing these systems in order to prevent unauthorised access or human breaches were underestimated at the outset of the trial. Data flows were complex in terms of source and type and ensuring highest technical security standards meant lengthy penetration tests were needed before approving their use. The complexity of these tests was exacerbated by the number of organisations involved and these issues took substantial time, incurred additional costs and required collaboration between ambulance service study sites, software providers, central health informatics units, and academic units resulting in slow progress and slippage of go-live dates. Solutions which helped resolve some of these issues were recruitment of internal Ambulance Service project managers and a full time researcher with an IT background to work on IT implementation issues and the initiation of small planning
group meetings between the SAFER 1 research team and key agencies. These difficulties persisted, particularly in matching the needs of the research team with complex technology as illustrated by comments presented in Figure 2.

**Figure 2: Project Reflections from research diaries**

<table>
<thead>
<tr>
<th>Management leadership</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research diary for researcher 1:</td>
</tr>
<tr>
<td>‘It seems that nothing can move forward without the express permission of a senior manager, everything is referred up, even the smallest of tasks, which takes time.’</td>
</tr>
<tr>
<td>email from senior research team member to senior ambulance service manager:</td>
</tr>
<tr>
<td>‘Many more personnel than expected or advised by us have been included in trial set up, which has resulted in duplication of information sharing and sometimes a lack of clear role allocation.’</td>
</tr>
</tbody>
</table>

| Research diary 2: |
| ‘The division of each project into bite size chunks of technical and non technical issues works well when the problem can be solved (or understood) within the project team itself. However, often issues were technically challenging and hard to understand, or even to disentangle the technical from the non-technical elements that needed to be actioned to drive things forwards. This often led to even greater complexity and lack of clarity of how best to resolve problems in the short term.’ |

| Collaboration and information sharing |
| DH funding report: |
| ‘Agreement of processes related to data storage and access, technical compatibility and research and information governance requirements are time intensive, system dependent and have changed over time with increasing bureaucracy’. |

| Research diary 1: |
| ‘I sometimes think we are talking a separate language. In the meeting today (25/09/09) it became apparent that we just didn’t understand the technical nature of the IT solutions anymore than they understood what we needed to make things work for us as researchers.’ |

| Support on the ground |
| This email from one of the operations managers to a researcher shows clearly that it was not easy for him to access his team: ‘I have arranged to facilitate the feedback sessions [from paramedics] next week-if I can pin them down.’ The paramedics weren’t his team, that was one of the problems - in the future this element of working together could be addressed better in the protocol – one of the learning outcomes is perhaps that this is, among other things, key |

**Support for the project on the ground**

Overt support at operational level was not always evident and communication with operational managers was difficult because of their busy timetables. Research within ambulance organisations was clearly not a priority compared to operational performance. Direct communication with paramedics who would be using the intervention was not allowed directly, but facilitated through operational managers which produced serious problems for the research team, for example in setting up training sessions, as information was not always passed to study paramedics. This should have been resolved at AS1 when an operational manager was part funded through NHS research support costs to provide a link between the
research team and the operations team but staff changes because of delays in the trial start date and operational priorities meant that continuity and commitment was sometimes lost and the benefits not fully realised. The communication difficulties affected intervention and control group adherence to the research protocol as they did not have the input needed to ensure they were operationally practical in the field. For example there were frequent events when there was signal loss so study paramedics could not access the CCDS but these issues remained unresolved throughout the trial. Data collection processes became unclear and cumbersome. The retrieval and matching of AS1 Patient Clinical Records (PCRs), completed by study paramedics at the scene of incidents was the most problematic part of the data collection pilot. Only 57% (19/33) of PCRs were retrieved during the data collection pilot week significantly reducing the verification of eligibility of patients. When data collection processes were made simple and the procedures were straightforward they tended to work. This happened most easily in AS5, where data collection processes were simplified and the real life situation of collecting information from paramedics was kept in mind because a paramedic helped design them.

**Study Costs**

One other consequence of the problems encountered during the SAFER 1 trial was the impact on study costs. Although some effects could be offset, for example by delaying recruitment of study staff, overall the increased costs associated with developing the intervention, protracted set up and implementation processes and initiating the complex data management processes meant that the final study costs to the funder increased by 40% from the £413,089 originally awarded to £574,637. In addition, the organisations participating in the study incurred substantial additional, unfunded costs due to the changing requirements related to IT, governance, and organisational performance. The involvement of study services was intended to be cost neutral but the complexity of the trial meant more resources were required resulting in study services being required to apply for associated costs from other sources. The work the IT companies did to develop the intervention ePRF and CCDS was substantial, although largely unfunded.

**Discussion**

It is known from other studies that NHS involvement in trials is heavily reliant on inter-organisational congruence [33]. Difficulties are compounded when implementing a complex IT intervention [34-36], where implementation is challenging in itself and data protection and data storage issues are sensitive [29,37,38]. The challenges imposed by the national policy initiative NPfIT and subsequent lack of progress also hindered progress. In order to overcome these issues, management at senior levels must be committed to a trial [39] and middle managers need the power to react quickly when confronted with unpredictable events [40]. This lack of power and influence is particularly evident when many stakeholders have to work together, some of whom may come from very different sections of the organisation such as IT or operations and may therefore have very different interests, skills and knowledge [41]. Without the full engagement of staff at all levels it is very difficult to plan and implement a meaningful RCT [42]. Successful implementation can be accomplished only when various stakeholders bridge their different institutional worlds [43,44], decision making processes are clarified and appropriate levels of management are introduced [35] and research is supported by senior management.

Implementing the SAFER 1 trial in the pre-hospital environment has had to meet all of these challenges. External events, outside the control of the project, can impede progress [87] and in SAFER 1 a number of key policy changes had a significant impact on both the development of the planned intervention and the ability to recruit and retain study sites. This combined with higher than expected workloads to implement the trial and develop and test information pathways led to a very significant delay in starting patient recruitment. Table 4 below illustrates the difficulties encountered with recruiting and retaining study sites.
Table 4: Key events by date in intervention development and site participants

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCDS</td>
<td>S1</td>
<td>S1</td>
<td>S1</td>
<td>S1</td>
<td>S1</td>
</tr>
<tr>
<td>ePRF</td>
<td>S1</td>
<td>S2</td>
<td>S2 &amp; S3</td>
<td>S2 &amp; S3</td>
<td>S2 &amp; S3</td>
</tr>
<tr>
<td>AS1</td>
<td>Recruited</td>
<td>Recruited</td>
<td>Recruited</td>
<td>Recruited</td>
<td>Recruited</td>
</tr>
<tr>
<td>AS2</td>
<td>Recruited</td>
<td>Withdraw</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS3</td>
<td>Recruited</td>
<td>Withdraw</td>
<td>Recruited &amp;Withdraw</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS4</td>
<td>Recruited</td>
<td>Withdraw</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS5</td>
<td>Recruited</td>
<td>Recruited</td>
<td></td>
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</tr>
</tbody>
</table>

The timing of the research trial was crucial to partners’ interest in the project and it was reflected in each organisation’s willingness to become involved [6]. A close match between interested organisations and the trial’s objectives means close alignment but the longer the implementation phase the more likely it becomes that the match between the interests of the partner organisation and the research trial objectives become incongruent [33]. Some organisations withdrew because of the tension between the trial requirements and their organisational capacity or objectives [8] with the demands of operational performance targets being a particularly big influence. More fundamentally, this illustrates the historical organisational culture in ambulance services where the emphasis and priorities have been on narrow performance measures and only more recently is this changing towards evidence based practice and quality clinical care.

The instability caused by external events and complexity of the environment in which the trial implementation process took place meant strong leadership and direction was important to make the trial actually happen [36]. Although there were signs of strong leadership at certain times and at various management levels, there was little evidence of real impetus and drive for the adoption and implementation of the trial [33]. Given the large number of other changes competing for senior managers’ attention during the implementation phase, the level of prioritisation of a technologically complex trial relative to other matters is an important consideration if a trial is to be successful [39] and both commitment at senior and middle management levels together with a clear decision making structure actually are needed [84]. In practice, prioritisation will probably only be achieved when directors include R&D goals in NHS senior manager objectives.

In SAFER 1 the lack of power and influence in middle management was particularly evident when many stakeholders had to work together, [41] and resulted in slow progress to arriving at the point where patient recruitment could start. The introduction of new technology in clinical settings involve far reaching changes to roles and workloads on the individuals involved and although these cannot be avoided their effects can be mitigated by good management, clear decision making structures, and devolved role assignment from the senior to the middle management [35]. Similarly, to overcome the external events and technical challenges an efficient and flexible cross partner trials management team is needed.

Of the many technical issues that the project encountered the boundaries that impede data sharing, consent and confidentiality and how knowledge is shared across institutional boundaries are some of the most pervasive [29,37,45]. There has been considerable debate and discussion in the literature about data sharing [37], consent and confidentiality [29,37, 38] and the processes of R&D and ethical approval [44-46]. It is recognised here that systematic changes to the way data is shared across organisations involved in health may be desirable but difficult to realize [44]. Issues relating to the protection of patient data and data sharing were numerous and exacerbated by insufficient understanding of the software and hardware within the research and management teams. This was eventually resolved when the various organisations were brought together within a project management framework that involved task driven small group meetings [35].
Although the research team can minimise the workload of those involved in operations, for instance by assisting with recruitment and informed consent, they cannot fully eliminate it. Recent data protection protocols are also making it increasingly difficult for researchers to support operational staff resulting in additional research burdens to participating sites. Without the full engagement of operational staff it is very difficult to plan and implement a meaningful RCT [42]. Adapting protocols, making them practical and relevant and simplifying the work required from practitioners must be a priority [3,34] and researchers working on trials that involve frontline staff need to be able to meet and design the project with those staff in mind [3,42]. In SAFER 1 the recruitment of a paramedic to support the research team resulted in significant progress in protocol development and information capture that helped ensure success once the trial got underway. Development of research skills within ambulance services will enhance these processes in the future. Similarly the research team need to understand the difficulties ambulance services face in trying to conduct research in an organization that also needs to maintain service delivery. In this way the abilities, skill sets and collaborative relationships needed across a range of organizations for delivery of a successful trial can be developed.

Conclusion

The challenges in implementing an RCT in emergency pre-hospital care are considerable. The use of the framework for evaluating complex interventions was of value and the experiences of SAFER 1 highlight the particular value of considering implementation issues and pilot studies ahead of conducting a main trial. The main lessons learned were concerned with trial set up in the pre-hospital environment and areas identified where improvements can be made are:

- Government level commitment to supporting and facilitating research in the emergency care environment: needs to be explicit
- Research capacity within ambulance service is still limited and needs building but will only happen when there are sufficient incentives to make research a priority so that it becomes a “must do” rather than a “nice to do”
- R&D goals in NHS senior manager objectives so that research becomes a priority and is properly supported at a senior level
- Appropriate levels of project management support within the research team and participating services
- Clarification of decision making processes at an early stage and the identification and involvement key stakeholders from the outset and clear communication lines
- Explicit support at the operational level
- Recognition by the research team of the conflicts between maintaining service delivery and conducting research that ambulance services face
- A need to appreciate the complexities of engaging in an IT based complex trial and the time needed to develop and test the intervention
- Stakeholders must be able to support research adequately and align their conflicting priorities in order to ensure trial implementation

Overall the story of the SAFER 1 trial shows that despite the considerable challenges it is possible to conduct a complex trial in the pre-hospital environment and the collaborative links developed during the course of the project have gone some way to helping build research capacity within the ambulance service. However, it is also clear there is still work to be done in gaining the cultural shift needed in ambulance services if research is to become a priority. On a wider scale more needs to be done to enable and support the further development of research capacity that will enable researchers and all emergency care organisations to work together. Within ambulance services it is still the case that the pressures of achieving performance targets outweigh any other activity and until incentives are in place to encourage and promote research as a desirable and indeed
essential activity the potential benefits of improving patient care by evaluating service
tchanges and strengthening the pre-hospital care evidence base will be slow to be
realised.
References


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Chapter 4 Clinical Effectiveness of Computerised Clinical Decision Support for emergency ambulance personnel

Title
Support and Assessment for Fall Emergency Referrals (SAFER) 1: Randomised trial to evaluate the clinical and cost effectiveness of computerised decision support software for emergency ambulance paramedics to use in the care of older people who have suffered a fall.

Abstract

Trial design
Cluster randomised trial in two UK emergency ambulance services to estimate the clinical and cost-effectiveness of computerised decision support software (CCDS) for paramedics to use in the face-to-face assessment and care of older people for whom an emergency call for a fall has been made, with paramedics as clusters.

Methods
Paramedics randomly allocated to the intervention group were trained and issued with the hardware and software required for the trial, to be used for older people who had fallen. Paramedics randomly allocated to the control group continued with standard care. Patients aged 65 or over for whom a call to the emergency ambulance service was coded by the call taker as a fall within the trial catchment areas were included. The principal outcomes for the trial were: onward pathway of care (referral to falls service; ED avoidance) – key process outcomes; and interval to the first subsequent emergency contact after the index call or death (event free period) – key safety outcomes. Secondary outcomes included: event-free period adjusted for patient-reported health-related quality of life; patient satisfaction; fall-related self-efficacy (fear of falling) and clinical and operational processes of care.

Results
Forty two paramedics volunteered to participate in the trial; 779 patients were included in analysis. There were no differences in participant characteristics between sites in age, sex or incident type, although the division of participants between trial arms varied by site (site 1 - intervention to controls 51:49; site 2 - 63:37). Reported CCDS usage was low at 12% (n = 54) of intervention group patients, although higher at site 2 than site 1 (24% versus 2%).

We found no differences between intervention and control groups in subsequent emergency healthcare contacts or death related to a fall or for any reason, or patient reported falls, quality of life, satisfaction or fear of falling. If nothing else, this confirms the safety of CCDS.

The proportion of patients referred to falls services was significantly higher in the intervention group than in the control group [adjusted proportions: 31/436 (7%) versus 13/343 (4%); relative risk 2.04 with 95% CI from 1.12 to 3.72]. The associated higher non-conveyance rate did not reach statistical significance [adjusted rates 179/436 (41%) versus 131/343 (38%); relative risk 1.13 with 95% CI from 0.84 to 1.52] and showed considerable differences between sites. Job cycle time was 8.56 minutes longer (95% CI 2.18 to 14.93). No differences were found in clinical documentation levels which exceeded 90% in both arms of the trial.

Reported CCDS usage varied widely between individual paramedics (0 – 22 times) but was associated with: non-conveyance [CCDS used = 35/54 (65%) not conveyed versus 274/725 (38%)]; and patient referred to falls service [CCDS used = 12/54 (22%) versus 47/725 (7%)].
Conclusions

With the low usage found in this trial, we could not have expected to find many effects on our nominal primary outcome of emergency healthcare contact or death by 1 month, owing to reduced power and the longer term nature of the intervention. However the CCDS did have an effect on decision making and pathways of care. Though infrequently used it affected the care of patients, when it was used and more widely, across the group of paramedics who were trained and had the CCDS ‘kit’. These encouraging findings highlight the potential for improving patient health outcomes, especially if uptake can be improved. With the higher rate of referrals found in this trial, the findings provide evidence to support the further development of CCDS in an integrated and user friendly format for further evaluation in services that are committed to completion of a fully powered trial.

Trial registration  ISRCTN10538608
Introduction

Background

Demand for immediate care through the emergency ambulance service has been steadily increasing across the UK and internationally over recent years [1]. However up to half of all callers have no clinical need for an emergency department (ED). This includes many older people who have fallen. Although health policy in the UK encourages emergency ambulance services to offer alternative services to such callers, there is little evidence about the safety and effectiveness of new models of care which depend on clinical assessment by ambulance staff to triage people to appropriate onward pathways of care.

Falls in older people are recognised internationally as an issue of increasing importance as populations age [2,3]. Costs are high to individuals, their carers and healthcare organisations. Reduction in quality of life and physical activity lead to social isolation and functional deterioration, with a high risk of dependency and institutionalisation [4-6]. In the UK, falls account for 3% of total National Health Service (NHS) expenditure [7], and the prevention of falls in older people is a priority [8,9]. Although prevention strategies are effective [9] reduction of falls, injuries and associated morbidity depend on early identification of people at high risk and delivery of interventions across traditional service boundaries [10], reflected in current national and international guidelines [11-13]. Evidence from randomised trials in emergency settings with similar groups suggests care offered by a multi-disciplinary falls service improves outcomes for patients [14-16].

Calls to emergency ambulance services (999 calls) for falls account for around 8% of the workload of urban Emergency Medical Service (EMS) systems internationally [17,18]. Perhaps 40% of these patients are not taken to hospital [17-20] but referral routes to other healthcare providers are rarely in place. Non-conveyance of patients attended by emergency ambulances is recognised internationally as a safety and litigation risk [21]. Most UK ambulance services have had guidelines suggesting that all patients be conveyed to the ED unless the patient refuses to travel to hospital. In practice, however, informal triage by ambulance staff to decide who can be safely left at home has been generally accepted by ambulance services across the UK. This is now changing, but evidence about safety and effectiveness is lagging behind practice development. Little is known about how, in the absence of specific protocols or training to leave older people who fall at home, ambulance staff make these decisions. However a US-based study recognised the pragmatic nature of the process of negotiation with the patient about whether to go to hospital [22]. In the UK, qualitative studies have found that crew members deciding whether to take patients to the ED, base decisions on ‘intuition’ (generally considered a source of error and bias [23]) and distance to receiving unit [24-26].

A recent systematic review of the effectiveness of multi-factorial assessment and targeted intervention for falls injury prevention in community and emergency settings concluded that there have been “few large-scale, high-quality randomised trials. Studies are needed that have the power to detect important effects on the number of fall-related injuries and quality of life, so as to resolve uncertainty about the clinical and cost effectiveness” [27] of falls interventions.

This trial addresses an important area of care for older people who fall. It tests a technological innovation applied in the context of the availability of a new care pathway. Following the hypothesised causal pathway, in order to improve outcomes for patients the CCDS needs to be acceptable to paramedics and patients, and to change practice so that paramedics make safe decisions to leave patients at the scene of their emergency attendance with appropriate referrals to falls services. Evaluation of the costs and benefits of this complex intervention will provide valuable information about the use of computerised decision support to plan care for older people who have suffered a fall, with the aim of avoiding unnecessary hospital admissions in this vulnerable patient group.
Objectives

The objectives of the trial were to estimate the effects of the intervention at one month on:

9. Pathway of care following attendance by an emergency ambulance paramedic for a fall
   o Referrals to falls service
   o Non-conveyance (ED avoidance)
10. Time to first subsequent emergency healthcare contact for a fall, or death
11. Time to first subsequent emergency healthcare contact for any reason, or death
    (‘event-free period’)
12. Event-free period adjusted by health-related quality of life
13. Quality of life of patients, including ‘fear of falling’, independence and satisfaction
14. Subsequent falls and fractures
15. Clinical and operational ‘process’ indicators:
   o Compliance with protocols including CCDS usage
   o Job cycle time – from 999 call to ‘ambulance free’ time
   o Length of emergency care episode – from 999 call to discharge of patient from ED
     or ambulance if not conveyed
16. NHS resource use

and at each participating site, to explore:

- implementation issues with service providers
- patient experience and views of the intervention

In this paper we present the methods and results of the trial related to clinical effectiveness -- objectives 1-7 above.

Methods

Trial Design

The trial was designed as a cluster randomised trial, with paramedics as clusters, to study the effects on patient outcomes of an intervention targeted at health professionals [28]. A cluster design was necessary, rather than randomisation of individual patients, as paramedics trained to use the CCDS would not be able to ‘switch on and off’ learned skills in the assessment and treatment of individual patients.

Important changes to methods after trial commencement

The trial was planned with three participating ambulance services and related acute trusts and falls service providers, with follow up of patient outcomes at one and six months. Alongside changes related to ambulance service reorganisation, performance pressures and delays in the timetable for implementation of the electronic patient report form (ePRF), several ambulance services expressed an interest in participating in the trial but withdrew (chapter 3). We eventually conducted the trial with two participating services, with a one month follow up only, after initial difficulties related to local ePRF adoption and associated challenges in meeting the paramedic recruitment targets. Whilst this meant that we were now unlikely to meet our target sample size, the Trial Steering Committee (TSC), research team and study funders agreed that worthwhile lessons could still be learned from the trial even if the effects were more likely to be found in the clinical and operational processes of care than the clinical or patient-reported outcomes of care.

Participants: eligibility criteria

Clusters: Paramedics based at ambulance stations in the catchment areas of partner falls services were invited to participate in the trial. Volunteers were consented and, at the close of recruitment, were randomly allocated to the intervention or control group.
Patients: People were eligible for the trial if they:

- were aged 65 or above
- had an emergency ambulance call made for them that was categorised as a fall without priority symptoms by the call taker
- were attended by a study paramedic
- lived in the catchment area of a participating falls service

Patients were recruited only once to the study i.e. for their first eligible call within the study period. Those living in nursing homes were excluded as they were not eligible for care provided by participating falls services.

**Setting**

The trial was undertaken in areas within two UK emergency ambulance services where a falls service referral pathway was available. Site 1 was an urban centre where paramedics were recruited from 4 ambulance stations; in site 2, paramedics were recruited from 9 stations across a wider mixed urban and rural area.

**Intervention and control practice**

The intervention evaluated was CCDS on a hand-held Tablet PC for use on scene by ambulance crews to make decisions about the clinical and social care needs of older patients who had fallen and generated a call to the emergency ambulance service. This complex intervention used CCDS during the face-to-face assessment and care of patients. Clinical and technology-based training formed the other key component of the intervention. The CCDS sat alongside an ePRF used for patient related documentation (condition, care and operational details), and a referral pathway to community based falls services – a prerequisite for the trial.

The CCDS was to be used to assess whether the older person who had fallen should be taken to the ED or offered an alternative care plan. The CCDS prompted the assessment and examination of any injuries associated with the fall, co-morbidity that might have contributed to the fall (such as breathlessness or chest pain), the patient’s psycho-social needs (such as their mental state and ability to undertake activities of daily living) and environmental risk. Based on the information about symptoms and examination findings that the paramedic input into the CDSS, it advised on whether the patient should be transported to an ED or could be provided with self-care advice (including written information) and referred to the falls service or their the GP or both. Training in use of the CCDS consisted of one half-day session, including systematic demonstration of the mechanics and functionality of the software coupled with practice and supervised role play. Following initial training there was a pre-trial period of up to one month during which trained crews practised using CCDS for falls assessment when appropriate. Critical reflection and discussion was undertaken and encouraged throughout the training programme. Knowledge reviews were carried out at certain points of the process to ensure competence and understanding of key aspects of the software functionality.

Reflecting local differences in information management systems, the intervention was introduced in different ways at the two trial sites.

**Site 1:** the hardware (individually issued Tablet PCs and printers installed in emergency vehicles) and software (ePRF and CCDS) were introduced specifically for the trial. Participating paramedics were asked to use both the ePRF and the CCDS during the trial – for the first time. Although the trial team proposed that the ePRF be used for all patients, and the CCDS then be used for patients who had suffered a fall, agreement was eventually reached with service managers that participating paramedics would use the IT intervention only for patients who had fallen in order to minimise any effects on operational performance.

**Site 2:** the hardware was already in place in emergency vehicles, and crews were already trained to use the ePRF, although the system had become optional and usage of the ePRF was low at the outset of the trial. Paramedic participants were therefore asked to use the CCDS for people who had suffered a fall in addition to using the ePRF for all patients.
Whilst the CCDS was provided at both sites by one software company, the ePRF was provided by different software companies and differed in data transfer technology and data linkage between NHS providers.

Control group practice reflected standard care at each site. Referral pathways were in place for people who had suffered a fall, and ambulance paramedics were able to assess patients and make decisions about whether to take the patient to the ED, or leave them at home with referral to a community-based falls service. Training, protocols, decision support tools and usual responses to falls varied between and within services, reflecting current practice. Whilst it was not possible to standardise practice in the control group, the following features were required for participation in the trial: paramedics in the control group should be trained in assessment skills for leaving patients at home rather than taking them to the ED; protocols and decision support tools should be paper-based; and a response to falls including multidisciplinary assessment should be available within 5 days.

**Outcomes**

All outcomes were measured at one month. Emergency healthcare contacts were defined in this study as contacts made with the emergency ambulance service (999 calls), ED attendances, and emergency admissions to hospital. Subsequent emergency healthcare contacts were classified as fall-related if the incident was coded as a fall or the patient sustained a fracture. Ambulance service job cycle time was defined as the period between the initial 999 call and the time when the crew reported free to attend another call. Length of episode of emergency care also included the period until discharge for patients taken to ED.

Ambulance service personnel identified patients eligible for inclusion in the trial from routinely available ambulance service information, in two stages. Potentially eligible patients were identified from control room records by standard electronic query at each site and eligibility was confirmed by retrieving paper or electronic patient record forms to check details such as age and home address. Patients were contacted by the ambulance service by post at their usual home and any temporary address like their hospital ward within 7 to 10 days of their index call, with a final deadline for first contact at 28 days after the fall. These letters informed them about the study, and offered patients (or carers, on their behalf) the opportunity to opt out of one or both aspects of follow up. They were asked to return a form if they did not wish to be contacted again or if they did not wish their medical details to be accessed for the study. The study was reviewed and given a favourable ethical opinion by the Research Ethics Committee for Wales.

At both sites identifiable data were retrieved from the ambulance service about subsequent emergency calls and referrals to falls services and their outcomes. At site 1 data were retrieved from a central databank which contains anonymised linked data from NHS acute care providers (ED attendances, emergency admissions to hospital and deaths). At site 2, identifiable data were retrieved from individual NHS acute care providers about ED attendances and emergency admissions to hospital; and from the national Demographic Batch Service about deaths.

**Principal outcomes:**

1. Onward pathway of care: proportion of patients referred to falls services; patients left at scene by their attending crew without conveyance to ED
2. Interval to the first subsequent emergency healthcare contact for any reason or death (‘event-free period’)
3. Interval to the first subsequent emergency healthcare contact for a fall or death
4. ‘Quality adjusted’ event-free period, adjusted by health-related quality of life (SF12) scores
Secondary outcomes:

- Health-related quality of life (SF12) [29]
- Patient satisfaction (Quality of Care Monitor)
- Fall-related self-efficacy ('fear of falling')
- Number of further falls and fractures
- Quality of care: clinical documentation; compliance by paramedics with CCDS; and patterns of use of CCDS

Operational indicators:

- Length of ambulance service job cycle
- Length of episode of emergency care

The nominal primary outcome (the second principal outcome above) comprises a hierarchy (or 'iceberg') of four events or stages of patients' progress through care: (1) subsequent 999 call (2) subsequent ED attendance (3) subsequent emergency admission or (4) death within a month (30 days) of the index fall (Figure 1).

Figure 1: Hierarchy of outcomes

These four stages are of different importance to patients and NHS, and also of different statistical power. Though death is of supreme importance, it is too rare to yield sufficient statistical power; in contrast subsequent 999 calls are more frequent and therefore statistically powerful but not so important as the other events. To combine these events into one single analysis would require methodological work to develop ordinal or weighted survival analysis. Instead we analysed these as four separable but related events, with the option of developing appropriate weights if we found evidence of differential effects, for example CCDS reducing 999 calls but increasing deaths.

To explore both direct and indirect effects of CCDS, we analysed both fall-related and non-fall-related events in this way. To explore the effects of CCDS on the timing of events, we analysed event-free intervals. To explore the effects of CCDS on quality of life, we adjusted event-free intervals (fall-related and non-fall related) by SF12, which led to another eight comparisons. Thus we tested the effect of the intervention on patient outcome through 24 distinct but related comparisons namely 4 stages x (fall or non-fall) x (timing or quality-adjusted timing or number).
Changes to trial outcomes after the trial commenced

Delays in implementing the intervention, and results of a data acquisition pilot, led us to drop some aspects of outcome measurement before we started to recruit patients, with the agreement of the Trial Steering Committee (TSC):

1. measurement of outcomes to 6 months – impractical within the funded period.
2. costs to patients and carers – because we shortened the questionnaire considerably to improve response rates.

With these changes, the relative importance of outcomes shifted, so that the clinical process indicators measuring steps in the hypothesised causal chain underpinning the study became the key outcomes that might indicate whether the intervention was, or was likely to be, clinically and cost effective.

Sample size

We designed the trial to detect clinically important changes in the primary outcome – the time to first subsequent reported fall (or death). As there are no published data on the distribution of time to first reported fall, we estimated the sample size conservatively, using the rate of subsequent falls (or deaths).

From data from participating ambulance services, we originally estimated that, with 20 active paramedics (ten in intervention group, and ten in control group) in each of three participating sites we could recruit 1500 patients during the study recruitment period, yielding more than 80% power when using a 5% significance level to detect a fall in the proportion of participants who make another emergency call for a fall within six months (or die) from 50% [30] to 40% if, as we projected, the intra-paramedic correlation coefficient (IPCC) was less than 0.035. Since this proportion is a binary variable, the time to first reported fall (or death), which is a continuous variable, would yield greater power. This sample size would also give us the power to detect an effect size of 0.20 (i.e. one fifth of the population standard deviation) in SF12 scores.

In reducing to two sites, we planned to recruit 40 paramedics in all. In dropping the 6-month follow up, we estimated that the proportion of participants making a further emergency call for a fall within one month would be closer to 30%, and that a reduction to 20% would be clinically significant. Experience in designing SAFER 2 (a trial in a similar patient group and setting which began after SAFER 1) led us to reduce the estimated IPCC to 0.02. Hence, if each paramedic were to recruit 22 patients, making 880 in all, our power to detect a clinically significant difference when using a 5% significance level would remain at 80%.

Randomisation

We invited paramedics based at ambulance stations in the catchment area of participating falls services to take part in the study. The West Wales Organisation for Randomised Trials in Health (WWORTH) allocated participating paramedics between intervention and control arms through simple randomisation. To minimise the danger of bias, randomisation took place after paramedics had joined the trial but before they started training to use the intervention. We replaced paramedics who withdrew after randomisation by allocating their replacements at random using a weighted probability favouring the depleted arm.

The trial statistician (WYC) and methodologist (ITR) remained blind to the identity of the anonymised groups until they had made all key decisions about the nature of the models to fit.

Statistical methods

Primary analysis was by ‘treatment allocated’, which is intrinsically unbiased because it follows the original random allocation. It also epitomises the pragmatic nature of the SAFER 1 trial, in the sense that it reflects the real world, where patients do not always receive, or comply with, the treatment prescribed for them. We also undertook analysis by ‘treatment received’ which, though potentially biased because it reflects human preferences, can throw light on the use of
the CCDS in practice. As potential covariates we identified in advance characteristics that might affect triage decisions, outcomes and data quality including: ambulance service; the participant’s age, gender and distance from home address to the nearest ED; whether the call was out of hours; and the ‘recruitment interval’, the time between the start of recruitment and the date of the call (which affects the chance that we receive notification of subsequent events).

We analysed event-free intervals and quality-adjusted event-free intervals by multi-level survival models. We analysed number of events, health-related quality of life, patient satisfaction and fear of falling by multi-level linear models. As these multi-level models did not significantly improve the fit achieved by simpler single-level models, however, we generally report the latter. We compared changes in place of residence and in the pathway of care by cross-tabulating by study group and estimating risk ratios and their confidence intervals. We compared operational indicators by mean differences between study groups and their 95% confidence intervals (from which one can readily derive two-tailed tests with a significance level of 5%).

Recruitment of patients

Researchers based within the ambulance services wrote to all patients confirmed as eligible for inclusion in the trial, ideally one week after their index call but with a limit of 28 days, to inform them about the trial and offer them the opportunity to opt out of completing postal questionnaires or allowing follow up of their routine medical records or both.

Results

Recruitment and participant flow

Site 1 recruited patients between 17 November 2009 and 31 October 2010, and Site 2 between 5 December 2009 and 31 October 2010. Figures 2, 3 and 4 show the flow of patients through the resulting cluster randomised trial, combined and at each site.

The proportion of eligible paramedics who volunteered to participate in the SAFER 1 trial varied between sites [Site 1: 26/40 (65%); Site 2: 15/362 (4.2%)]. Cluster allocation between intervention and control groups was equal (21:21), but lower availability of control paramedics due to long term sickness or withdrawal from the trial during the recruitment period at site 2 (intervention total = 282 weeks; control total = 154 weeks) meant that patient recruitment was higher in the intervention group than the control group. Fortunately there was little loss of statistical power from this imbalance.

In the only protocol deviation an intervention paramedic did not receive training, hardware or software. He remained in the intervention group for analysis by treatment allocated.

A high proportion of eligible patients were sent letters offering the opportunity to opt out of the trial (96% in intervention group; 94% in control group). Across both arms of the trial 27% of patients opted out of further participation in the trial (intervention group 29%; control group 25%), leaving 779 patients in the trial for analysis, close to our revised target of 880.
Figure 2: CONSORT flowchart for progress of clusters and individuals through RCT adapted to circumstances of SAFER 1

No of clusters (paramedics) available = 402
No of paramedics who did not volunteer = 360
No of paramedics volunteered = 42

Paramedics allocated to intervention: total number of clusters = 21
Long term sick = 2; Withdrew = 2
Confirmed intervention paramedics: total = 17
average per paramedic = 61.41; range per paramedic = 27-138

Paramedics allocated to control: total number of clusters = 21
Long term sick = 2; Withdrew = 1
Confirmed control paramedics: total = 18
average per paramedic = 44.67; range per paramedic = 2-128

Patients not contacted to opt out: total = 26; no of paramedics = 9; average per paramedic = 2.89; range per paramedic = 1-5
- Incorrect contact details: total = 23; no of paramedics = 8; average per paramedic = 2.88; range per paramedic = 2-5
- Others:
  - patient refused to be contacted: total = 1; no of paramedics = 1; average per paramedic = 1; range per paramedic = 1-1
  - patient with cardiac arrest: total = 1; no of paramedics = 1; average per paramedic = 1; range per paramedic = 1-1
  - patient known to be deceased: total = 1; no of paramedics = 1; average per paramedic = 1; range per paramedic = 1-1

Patients opted out: total = 174; no of paramedics = 17; average per paramedic = 10.24; range per paramedic = 5-17
- Opted out of entire trial: total = 168; no of paramedics = 17; average per paramedic = 9.88; range per paramedic = 4-15
- Opted out of routine data only: total = 6; no of paramedics = 5; average per paramedic = 1.2; range per paramedic = 1-2

Analysed: total no of patients = 436; no of paramedics = 17; average per paramedic = 25.65; range per paramedic = 8-49

Used CCDS = 54
Not Used CCDS = 382

Patients excluded: total = 408; no of paramedics = 17; average per paramedic = 24; range per paramedic = 7-72
- Did not meet inclusion criteria: total = 307; no of paramedics = 17; average per paramedic = 18.06; range per paramedic = 5-52
- Insufficient information to confirm eligibility: total = 101; no of paramedics = 17; average per paramedic = 5.94; range per paramedic = 1-24

Patients not contacted to opt out: total = 31; no of paramedics = 18; average per paramedic = 17.61; range per paramedic = 2-62
- Did not meet inclusion criteria: total = 236; no of paramedics = 18; average per paramedic = 13.11; range per paramedic = 2-54
- Insufficient information to confirm eligibility: total = 8; no of paramedics = 12; average per paramedic = 6.75; range per paramedic = 2-16

Patients opted out: total = 113; no of paramedics = 17; average per paramedic = 6.65; range per paramedic = 1-18
- Opted out of entire trial: total = 112; no of paramedics = 17; average per paramedic = 6.59; range per paramedic = 1-18
- Opted out of routine data only: total = 1; no of paramedics = 1; average per paramedic = 1; range per paramedic = 1-1

Analysed: total no of patients = 343; no of paramedics = 17; average per paramedic = 20.18; range per paramedic = 4-47

*One paramedic became unwell at an early stage and only attended patients that were excluded owing to ineligibility. This paramedic is therefore excluded from this box onwards.
**Figure 3: CONSORT flowchart for the progress of clusters and individuals through RCT adapted to the special circumstances of SAFER 1 – Site 1**

- **No of clusters (paramedics) available = 40**
- **No of paramedics who did not volunteer = 14**

### Paramedics allocated to intervention: total number of clusters = 13
- **Long term sick = 2; Withdrew = 2**

### Confirmed intervention paramedics: total = 9
- **Average per paramedic = 51.22; Range per paramedic = 37-66**

### Patients potentially eligible total = 461 (999 call categorised by the call taker as a fall without priority symptoms allocated to study paramedic aged 65+ or age unknown); no of paramedics = 9; average per paramedic = 51.22; range per paramedic = 37-66

- **Patients excluded: total = 111; no of paramedics = 9; average per paramedic = 12.33; range per paramedic = 7-19**
  - Did not meet inclusion criteria: total = 86; no of paramedics = 9; average per paramedic = 9.56; range per paramedic = 5-17
  - Insufficient information to confirm eligibility (Form completed by attending crew not received): total = 25; no of paramedics = 9; average per paramedic = 2.78; range per paramedic = 1-6

- **Patients confirmed as eligible for inclusion in trial: total = 350; no of paramedics = 9; average per paramedic = 38.89; range per paramedic = 29-49**

### Offered opportunity to opt out: total = 326; no of paramedics = 9; average per paramedic = 36.22; range per paramedic = 21-46

- **Patients opted out: total = 24; no of paramedics = 8; average per paramedic = 3; range per paramedic = 1-5**
  - Incorrect contact details: total = 21; no of paramedics = 7; average per paramedic = 3; range per paramedic = 2-5
  - Others:
    - Patient refused to be contacted: total = 1; no of paramedics = 1; average per paramedic = 1; range per paramedic = 1-1
    - Patient had cardiac arrest: total = 1; no of paramedics = 1; average per paramedic = 1; range per paramedic = 1-1
    - Patient had head injuries: total = 1; no of paramedics = 1; average per paramedic = 1; range per paramedic = 1-1

- **Patients not contacted to opt out: total = 27; no of paramedics = 10; average per paramedic = 2.7; range per paramedic = 1-7**
  - Incorrect contact details: total = 26; no of paramedics = 10; average per paramedic = 2.6; range per paramedic = 1-7
  - Others:
    - Patient refused to be contacted: total = 0; no of paramedics = 0; average per paramedic = 0
    - Unable to locate PCR: total = 0; no of paramedics = 0; average per paramedic = 0
    - Patient had head injuries: total = 1; no of paramedics = 1; average per paramedic = 1; range per paramedic = 1-1

### Analyzed: total no of patients = 235; no of paramedics = 9; average per paramedic = 26.11; range per paramedic = 18-34

- **Used CCDS = 5**
- **Not Used CCDS = 230**

### Paramedics allocated to control: total number of clusters = 13
- **Long term sick = 1; Withdrew = 0**

### Confirmed control paramedics: total = 12
- **Average per paramedic = 39.58; Range per paramedic = 2-68**

### Patients potentially eligible total = 475 (999 call categorised by the call taker as a fall without priority symptoms allocated to study paramedic aged 65+ or age unknown); no of paramedics = 12; average per paramedic = 39.58; range per paramedic = 2-68

- **Patients excluded: total = 149; no of paramedics = 12; average per paramedic = 12.42; range per paramedic = 2-27**
  - Did not meet inclusion criteria: total = 108; no of paramedics = 12; average per paramedic = 9; range per paramedic = 2-17
  - Insufficient information to confirm eligibility (Form completed by attending crew not received): total = 41; no of paramedics = 7; average per paramedic = 5.88; range per paramedic = 1-10

- **Patients confirmed as eligible for inclusion in trial: total = 326; no of paramedics = 11; average per paramedic = 38.89; range per paramedic = 29-49**

### Offered opportunity to opt out: total = 299; no of paramedics = 11; average per paramedic = 27.18; range per paramedic = 16-46

- **Patients opted out: total = 91; no of paramedics = 9; average per paramedic = 10.11; range per paramedic = 5-16**
  - Opted out of entire trial: total = 68; no of paramedics = 9; average per paramedic = 9.77; range per paramedic = 5-15
  - Opted out of routine data only: total = 3; no of paramedics = 3; average per paramedic = 1; range per paramedic = 1-1

- **Patients not contacted to opt out: total = 27; no of paramedics = 10; average per paramedic = 2.7; range per paramedic = 1-7**
  - Incorrect contact details: total = 26; no of paramedics = 10; average per paramedic = 2.6; range per paramedic = 1-7
  - Others:
    - Patient refused to be contacted: total = 0; no of paramedics = 0; average per paramedic = 0
    - Unable to locate PCR: total = 0; no of paramedics = 0; average per paramedic = 0
    - Patient had head injuries: total = 1; no of paramedics = 1; average per paramedic = 1; range per paramedic = 1-1

### Analyzed: total no of patients = 225; no of paramedics = 11; average per paramedic = 20.45; range per paramedic = 12-33

*One paramedic became unwell at an early stage and only attended patients that were excluded owing to ineligibility. This paramedic is therefore excluded from this box onwards.*
Participants

Paramedics allocated to intervention: total number of clusters = 8
Long term sick = 0; Withdrew = 0
Confirmed intervention paramedics: total = 8

Patients potentially eligible total = 583 (999 call categorised by the call taker as a fall without priority symptoms allocated to study paramedic aged 65+ or age unknown); no of paramedics = 8; average per paramedic = 72.88; range per paramedic = 27-128

Patients excluded: total = 297; no of paramedics = 8; average per paramedic = 37.13; range per paramedic = 11-72
- Did not meet inclusion criteria: total = 221; no of paramedics = 8; average per paramedic = 27.63; range per paramedic = 10-52
- Insufficient information to confirm eligibility (Form completed by attending crew not received): total = 76; no of paramedics = 8; average per paramedic = 9.5; range per paramedic = 1-24

Patients confirmed as eligible for inclusion in trial: total = 286; no of paramedics = 8; average per paramedic = 35.75; range per paramedic = 13-66

Offered opportunity to opt out: total = 284; no of paramedics = 8; average per paramedic = 35.5; range per paramedic = 13-66

Patients not contacted to opt out: total = 2; no of paramedics = 1; average per paramedic = 2; range per paramedic = 2-2
- Incorrect contact details: total = 2; no of paramedics = 1; average per paramedic = 2; range per paramedic = 2-2
- Others:
  - patient refused to be contacted: total = 0; no of paramedics = 0; average per paramedic = 0
  - patient had cardiac arrest: total = 0; no of paramedics = 0; average per paramedic = 0
  - patient had head injuries: total = 0; no of paramedics = 0; average per paramedic = 0

Patients opted out: total = 83; no of paramedics = 8; average per paramedic = 10.38; range per paramedic = 5-17
- Opted out of entire trial: total = 88; no of paramedics = 8; average per paramedic = 10; range per paramedic = 4-15
- Opted out of routine data only: total = 3; no of paramedics = 2; average per paramedic = 1.5; range per paramedic = 1-2

Analysed: total no of patients = 201; no of paramedics = 8; average per paramedic = 25.13; range per paramedic = 8-49
- Used CCDS = 49
- Not Used CCDS = 152

Paramedics allocated to control: total number of clusters = 8
Long term sick = 1; Withdrew = 1
Confirmed control paramedics: total = 6

Patients potentially eligible total = 329 (999 call categorised by the call taker as a fall without priority symptoms allocated to study paramedic aged 65+ or age unknown); no of paramedics = 6; average per paramedic = 54.83; range per paramedic = 17-128

Patients excluded: total = 168; no of paramedics = 6; average per paramedic = 28; range per paramedic = 9-62
- Did not meet inclusion criteria: total = 128; no of paramedics = 6; average per paramedic = 21.33; range per paramedic = 3-54
- Insufficient information to confirm eligibility (Form completed by attending crew not received): total = 40; no of paramedics = 5; average per paramedic = 8; range per paramedic = 4-12

Patients confirmed as eligible for inclusion in trial: total = 161; no of paramedics = 6; average per paramedic = 26.83; range per paramedic = 6-66

Offered opportunity to opt out: total = 157; no of paramedics = 6; average per paramedic = 26.17; range per paramedic = 6-65

Patients not contacted to opt out: total = 4; no of paramedics = 3; average per paramedic = 1.33; range per paramedic = 1-2
- Incorrect contact details: total = 2; no of paramedics = 2; average per paramedic = 1; range per paramedic = 1-1
- Others:
  - patient refused to be contacted: total = 0; no of paramedics = 0; average per paramedic = 0
  - Unable to locate PCR: total = 2; no of paramedics = 2; average per paramedic = 1; range per paramedic = 1-1
  - patient had head injuries: total = 0; no of paramedics = 0; average per paramedic = 0

Patients opted out: total = 39; no of paramedics = 6; average per paramedic = 6.5; range per paramedic = 1-18
- Opted out of entire trial: total = 38; no of paramedics = 6; average per paramedic = 6.33; range per paramedic = 1-18
- Opted out of routine data only: total = 1; no of paramedics = 1; average per paramedic = 1; range per paramedic = 1-1

Analysed: total no of patients = 118; no of paramedics = 6; average per paramedic = 19.67; range per paramedic = 4-47
- Used CCDS = 49
- Not Used CCDS = 152
Over 90% of calls categorised as a fall by the call taker were also categorised by the crew as a fall or judged by the research team as likely to be fall-related e.g. fractured neck of femur, laceration or head injury. This demonstrates high validity of the trial patient recruitment process, adopted to minimise selection bias by crews.

Recorded CCDS usage was low in both sites (12% of intervention participants), but especially so in site 1 [5/235 (2%) compared with 49/201 (24%) in site 2]. We doubt that the recorded usage in site 1 was accurate, as it varied markedly across the study period and was inconsistent with qualitative data from participating paramedics (Chapter 6). Figure 5 shows attempted and actual usage before and throughout the patient recruitment period at site 1, and reveals a very erratic pattern, with a high level of attempts (log-ins) before the trial started, as paramedics were encouraged to practise after training and before the trial going ‘live’. During the study period, however, attempts were very few, and virtually zero for several months, conflicting with qualitative findings (chapter 6). Large diamonds indicate the five occasions of use for study patients. Other patients for whom records were successfully created did not meet the inclusion criteria for the trial, or opted out of follow up.

![Fig 5: Site 1 CCDS usage - successful log ons and CCDS records created](image-url)
Data about emergency healthcare contacts within one month (and deaths) retrieved through the identifiable and anonymised routes were at similar levels (Table 1).

**Table 1: (Percentage) of patients matched**

<table>
<thead>
<tr>
<th>Information about event</th>
<th>Site 1</th>
<th>Site 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Identifiable data from sites (n=460)</td>
<td>Anonymised data linkage (n=460)</td>
</tr>
<tr>
<td>999</td>
<td>460 (100%)</td>
<td>Not available</td>
</tr>
<tr>
<td>ED attendance</td>
<td>Not sought</td>
<td>Probability of correct match &gt; 80%: 420 (91%)</td>
</tr>
<tr>
<td>Inpatient admission</td>
<td>Not sought</td>
<td>Probability of correct match &gt; 90%: 412 (90%)</td>
</tr>
<tr>
<td>Deaths</td>
<td>Not sought</td>
<td>Perfect match: 339 (74%)</td>
</tr>
</tbody>
</table>

**Note:** Of the 40 participants not matched with probability at least 80%, SAIL could not match 36 at all, and matched the other 4 with probability less than 80%.

Table 2 shows that there were no differences at baseline between groups except for the proportion of participants by site: more patients were recruited to the trial from site 1 than site 2, and furthermore this difference was exacerbated in the control arm by the imbalance between arms at site 2.

**Table 2: Characteristics of participants recruited to Intervention and Control groups**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention (n=436)</th>
<th>Control (n=343)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men (%): Women (%)</td>
<td>153 (35%): 283 (65%)</td>
<td>132 (39%): 211 (61%)</td>
</tr>
<tr>
<td>Median age in years (interquartile range)</td>
<td>83 (77-89)</td>
<td>82 (76-88)</td>
</tr>
<tr>
<td>Site 1 (%): Site 2 (%)</td>
<td>235 (54%): 201 (46%)</td>
<td>225 (66%): 118 (34%)</td>
</tr>
<tr>
<td>Made index call out of hours (%)</td>
<td>256 (59%)</td>
<td>189 (55%)</td>
</tr>
<tr>
<td>Type of incident (n = 379)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fall (%)</td>
<td>197 (52%)</td>
<td>133 (46%)</td>
</tr>
<tr>
<td>Injury, presumed fall (%)</td>
<td>145 (38%)</td>
<td>131 (45%)</td>
</tr>
<tr>
<td>Total probable fall</td>
<td>342 (90%)</td>
<td>264 (91%)</td>
</tr>
</tbody>
</table>
Sixty one per cent of patients who did not opt out or die responded to postal questionnaires, a proportion that was reassuringly consistent across groups and sites (Table 3).

**Table 3: Questionnaire response rate**

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Site 1</td>
<td>Site 2</td>
<td>Site 1</td>
</tr>
<tr>
<td>No of eligible patients</td>
<td>235</td>
<td>201</td>
<td>225</td>
</tr>
<tr>
<td>No of patients who declined questionnaire follow up</td>
<td>2</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>No of patients who died</td>
<td>11</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>No of questionnaires returned</td>
<td>129</td>
<td>117</td>
<td>123</td>
</tr>
<tr>
<td>Response rate</td>
<td>58.1%</td>
<td>63.9%</td>
<td>58.3%</td>
</tr>
</tbody>
</table>

There was no significant difference in the distribution of patients seen by paramedics in Intervention and Control sites (Table 4).

**Table 4: Characteristics of Intervention and Control clusters**

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of paramedics</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>No of patients attended by paramedics</td>
<td>minimum</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>maximum</td>
<td>49</td>
</tr>
<tr>
<td></td>
<td>average</td>
<td>25.65</td>
</tr>
</tbody>
</table>

**Principal outcomes**

Given the intrinsic differences between sites in SAFER 1, it was not surprising that many effects estimated by SAFER 1 also differed between sites. To characterise these effects as accurately and as helpfully as possible, we adopted a staged analytical strategy, illustrated by Table 5. Having tabulated the observed data (which take the form of frequencies in Table 5), we estimated the ‘full statistical model’ specifying the effects of group (intervention versus control), site, interaction between group and site, and all other significant covariates. To ensure that the final ‘reduced model’ used as few parameters as possible (‘parsimonious parameterisation’), we then removed site or interaction or both if they were not significant.

In the right-hand column of Table 5 the observed referral rate to falls services was twice as high in patients attended by paramedics in the intervention group as in patients in the control
group. This pattern was similar in both sites, even though referral rates differed between them. Hence the reduced model showing significant effects of group and site is the best available summary of the effects of the CCDS on referrals to falls services in the SAFER 1 trial. Following the same logic we found no significant effect of CCDS on non-conveyance rates across the trial, even though these rates differed significantly between sites (left-hand column of Table 5).

**Table 5: Pathway of Care**

<table>
<thead>
<tr>
<th></th>
<th>Observed frequencies</th>
<th>Reduced model with significant covariates:</th>
<th>Full model incorporating group, site &amp; group-site interaction &amp; all significant covariates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
<td></td>
</tr>
<tr>
<td>Non-Conveyed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Site 1</td>
<td>Site 1: frequencies adjusted by significant covariates</td>
<td>Relative risk for Group adjusted by Site, interaction (95% CI); significance level</td>
</tr>
<tr>
<td></td>
<td>Observed frequencies</td>
<td>77</td>
<td>0.836 (0.529, 1.321)</td>
</tr>
<tr>
<td></td>
<td>85</td>
<td>63%</td>
<td>P=0.442</td>
</tr>
<tr>
<td></td>
<td>36%</td>
<td>30%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Site 2</td>
<td>Site 2: frequencies adjusted by significant covariates</td>
<td>Relative risk for Site adjusted by Group &amp; interaction (95% CI); sig level</td>
</tr>
<tr>
<td></td>
<td>Observed frequencies</td>
<td>101</td>
<td>0.353 (0.222, 0.563)</td>
</tr>
<tr>
<td></td>
<td>98</td>
<td>55%</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>49%</td>
<td>47%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Combined</td>
<td>Combined frequencies adjusted by sig covariates</td>
<td>Relative risk for interaction between Group &amp; Site (95% CI); significance level</td>
</tr>
<tr>
<td></td>
<td>Observed frequencies</td>
<td>179</td>
<td>1.693 (0.925, 3.097)</td>
</tr>
<tr>
<td></td>
<td>183</td>
<td>41%</td>
<td>P=0.088</td>
</tr>
<tr>
<td></td>
<td>36%</td>
<td>38%</td>
<td></td>
</tr>
<tr>
<td>Referral to Fall Services</td>
<td>Out of hours (P=0.018)</td>
<td>77</td>
<td>Relative risk for Site adjusted by Group &amp; interaction (95% CI); sig level</td>
</tr>
<tr>
<td></td>
<td>Site (P&lt;0.001)</td>
<td>63%</td>
<td>0.482 (0.358, 0.648)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>30%</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12</td>
<td>Relative risk for Group adjusted by Site, interaction (95% CI); significance level</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5%</td>
<td>2.643 (1.107, 6.266)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6%</td>
<td>P=0.028</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>21</td>
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<tr>
<td></td>
<td></td>
<td>7%</td>
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<td>13</td>
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<td>13</td>
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<td>4%</td>
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<td>3%</td>
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<td>5%</td>
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<td>5%</td>
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<td>13</td>
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<td></td>
<td></td>
<td>4%</td>
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<tr>
<td></td>
<td></td>
<td>0.462 (0.263, 0.810)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>P=0.007</td>
<td></td>
</tr>
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<td></td>
<td></td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.660 (0.243, 1.792)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>P=0.415</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.693 (0.925, 3.097)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>P=0.088</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.89 (0.174, 2.000)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>P=0.396</td>
<td></td>
</tr>
</tbody>
</table>

Table 6 and the following survival curves (Figures 6 and 7) show no differences between intervention and control groups, at either site or combined, in health outcomes at any level of the hierarchical primary outcome, whether or not adjusted by quality of life scores.
## Table 6: Number of people who remained event free at 30 days by group and site

<table>
<thead>
<tr>
<th>Event</th>
<th>Any cause</th>
<th>Fall-specific</th>
<th>Adjusted by SF6D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1: Intervention n = 235</td>
<td>Site 1: Control n = 225</td>
<td>Site 2: Intervention n = 201</td>
<td>Site 2: Control n = 118</td>
</tr>
<tr>
<td><strong>Death</strong> (no significant covariate)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 1: observed alive at 30 days</td>
<td>224I (95%): 216C (95%)</td>
<td>Not available</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Site 2: observed alive at 30 days</td>
<td>193I (96%): 116C (98%)</td>
<td>Not available</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Both sites: observed alive at 30 days</td>
<td>417I (96%): 332C (97%)</td>
<td>Not available</td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Full model</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event hazard-ratio for Group (95% CI); significance level</td>
<td>0.454 (0.096, 2.139) P = 0.318</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hazard-ratio for interaction between Group &amp; Site (95% CI); sig level</td>
<td>1.887 (0.318, 11.22) P = 0.485</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Death or admission</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 1: observed event-free @ 30dys</td>
<td>200I (85%): 191C (85%)</td>
<td>214I (91%): 203C (90%)</td>
<td></td>
</tr>
<tr>
<td>Site 2: observed event-free @ 30 dys</td>
<td>183I (91%): 109C (92%)</td>
<td>192I (96%): 115C (98%)</td>
<td></td>
</tr>
<tr>
<td>Both sites: observed event-free @30</td>
<td>383I (88%): 300C (88%)</td>
<td>406I (93%): 318C (93%)</td>
<td>383I (88%): 300C (88%)</td>
</tr>
<tr>
<td>Significant covariates:</td>
<td>Recruitment interval (P = 0.009); out of hours (P = 0.049)</td>
<td>Recruitment interval (P = 0.014)</td>
<td>Questionnaire status (P = 0.003); recruitment interval (P = 0.028)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both sites: adjusted event-free @ 30</td>
<td>389I (89%): 305C (89%)</td>
<td>426I (98%): 328 (96%)</td>
<td>406I (93%): 320C (93%)</td>
</tr>
<tr>
<td><strong>Full model</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event hazard-ratio for Group (95% CI); significance level</td>
<td>0.846 (0.378, 1.892) P = 0.684</td>
<td>0.530 (0.143, 1.969) P = 0.343</td>
<td>0.832 (0.371, 1.865), P = 0.656</td>
</tr>
<tr>
<td>Hazard-ratio for interaction between Group &amp; Site (95% CI); sig level</td>
<td>1.274 (0.500, 3.248), P = 0.612</td>
<td>2.188 (0.143, 1.969) P = 0.289</td>
<td>1.291 (0.506, 3.296), P = 0.593</td>
</tr>
<tr>
<td><strong>Death or admission or Emergency Department attendance</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 1: observed event-free @ 30dys</td>
<td>176I (75%): 173C (77%)</td>
<td>210I (89%): 202C (90%)</td>
<td></td>
</tr>
<tr>
<td>Site 2: observed event-free @ 30dys</td>
<td>166I (83%): 102C (86%)</td>
<td>183I (91%): 110C (93%)</td>
<td></td>
</tr>
<tr>
<td>Both sites: observed event-free @30</td>
<td>342I (78%): 275C (80%)</td>
<td>393I (90%): 312C (91%)</td>
<td>342I (78%): 275C (80%)</td>
</tr>
<tr>
<td>Significant covariates:</td>
<td>Recruitment interval (P = 0.005); out of hours (P = 0.036)</td>
<td>None</td>
<td>Questionnaire status (P &lt; 0.001); recruitment interval (P = 0.015); out of hours (P = 0.024)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both sites: adjusted event-free @ 30</td>
<td>361I (83%): 276C (80%)</td>
<td>As observed</td>
<td>370I (85%): 302C (88%)</td>
</tr>
<tr>
<td><strong>Full model</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event hazard-ratio for Group (95% CI); significance level</td>
<td>0.678 (0.363, 1.265) P = 0.222</td>
<td>0.700 (0.292, 1.675) P = 0.423</td>
<td>0.646 (0.345, 1.207), P = 0.170</td>
</tr>
<tr>
<td>Hazard-ratio for interaction between Group &amp; Site (95% CI); sig level</td>
<td>1.396 (0.674, 2.892) P = 0.370</td>
<td>1.369 (0.484, 3.875) P = 0.554</td>
<td>1.456 (0.702, 3.019) P = 0.313</td>
</tr>
<tr>
<td>Site 1: observed event-free @ 30dys</td>
<td>153I (65%): 150C (67%)</td>
<td>195I (83%): 184C (82%)</td>
<td></td>
</tr>
<tr>
<td>Site 2: observed event-free @ 30dys</td>
<td>128I (64%): 82C (70%)</td>
<td>158I (79%): 96C (81%)</td>
<td></td>
</tr>
<tr>
<td>Both sites: observed event-free @30</td>
<td>281I (64%): 232C (68%)</td>
<td>353I (81%): 280C (82%)</td>
<td>281I (64%): 232C (68%)</td>
</tr>
<tr>
<td>Significant covariates:</td>
<td>Recruitment interval (P=0.007); out of hours (P=0.016)</td>
<td>Out of hours (P=0.021)</td>
<td>Questionnaire status (P=0.002); out of hours (P=0.019); recruitment interval (P=0.016)</td>
</tr>
<tr>
<td>Both sites: adjusted event-free @ 30</td>
<td>289I (66%): 217C (63%)</td>
<td>356I (81%): 279 (81%)</td>
<td>292I:241 (67%:70%)</td>
</tr>
<tr>
<td><strong>Full model</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event hazard-ratio for Group (95% CI), significance level</td>
<td>0.753 (0.494, 1.146) P=0.185</td>
<td>0.888 (0.520, 1.516) P=0.664</td>
<td>0.738 (0.484, 1.124) P=0.157</td>
</tr>
<tr>
<td>Hazard-ratio for interaction between Group &amp; Site (95% CI), sig level</td>
<td>1.306 (0.771, 2.213) P=0.320</td>
<td>1.272 (0.635, 2.548) P=0.498</td>
<td>1.357 (0.800, 2.299) P=0.257</td>
</tr>
</tbody>
</table>

* Shaded cells display key features of full statistical model in response to reviewers’ comments
Figure 6: Survival curve for events of any cause

Event 4 = death, inpatient admission, emergency department attendance or 999 call

Figure 7: Survival curve for fall-related events

Event 3 = death, fall-related admission, emergency department attendance or 999 call
Table 7: Patient satisfaction & health-related quality of life scores by group and site

<table>
<thead>
<tr>
<th></th>
<th>Interventions</th>
<th>Control</th>
<th>Interventions</th>
<th>Control</th>
<th>Interventions</th>
<th>Control</th>
<th>Interventions</th>
<th>Control</th>
<th>Interventions</th>
<th>Control</th>
<th>Interventions</th>
<th>Control</th>
<th>Fear of falls</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quality care - technical</td>
<td>Q of care - interpersonal</td>
<td>SF12 MCS</td>
<td>SF12 PCS</td>
<td>SF6D</td>
<td>Q of care - technical</td>
<td>Q of care - interpersonal</td>
<td>SF12 MCS</td>
<td>SF12 PCS</td>
<td>SF6D</td>
<td>Q of care - technical</td>
<td>Q of care - interpersonal</td>
<td>SF12 MCS</td>
</tr>
<tr>
<td>Site 1</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
</tr>
<tr>
<td>Observed scores:</td>
<td>98.02</td>
<td>8.20</td>
<td>118</td>
<td>98.30</td>
<td>10.17</td>
<td>108</td>
<td>94.82</td>
<td>9.36</td>
<td>110</td>
<td>94.51</td>
<td>9.61</td>
<td>57</td>
<td>93.56</td>
</tr>
<tr>
<td>Site 2</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
</tr>
<tr>
<td>Observed scores:</td>
<td>97.58</td>
<td>12.94</td>
<td>110</td>
<td>97.95</td>
<td>7.76</td>
<td>57</td>
<td>94.51</td>
<td>9.61</td>
<td>102</td>
<td>94.18</td>
<td>12.19</td>
<td>54</td>
<td>91.48</td>
</tr>
<tr>
<td>Both sites</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
</tr>
<tr>
<td>Observed scores:</td>
<td>97.81</td>
<td>10.73</td>
<td>228</td>
<td>98.18</td>
<td>9.39</td>
<td>113</td>
<td>94.67</td>
<td>9.46</td>
<td>212</td>
<td>92.84</td>
<td>10.49</td>
<td>155</td>
<td>91.52</td>
</tr>
<tr>
<td>Significant</td>
<td>None</td>
<td>Distance to Emergency Department (P=0.015)</td>
<td>None</td>
<td>Questions needed help (P=0.001); sex (P=0.003)</td>
<td>Questions needed help (P&lt;0.001); sex (P=0.005)</td>
<td>Questionnaire needed help (P&lt;0.001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>covariates:</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Questions needed help (P=0.001); sex (P=0.003)</td>
<td>Questions needed help (P&lt;0.001); sex (P=0.005)</td>
<td>Questionnaire needed help (P&lt;0.001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjusted scores:</td>
<td>Site 1</td>
<td></td>
<td>Site 2</td>
<td></td>
<td></td>
<td>Both sites</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>As observed</td>
<td>95.13</td>
<td>93.82</td>
<td>As observed</td>
<td>93.51</td>
<td>91.52</td>
<td>As observed</td>
<td>93.35</td>
<td>93.02</td>
<td>As observed</td>
<td>94.35</td>
<td>93.02</td>
<td>As observed</td>
</tr>
<tr>
<td>N</td>
<td>105</td>
<td>97</td>
<td>98</td>
<td>98</td>
<td>98</td>
<td>98</td>
<td>203</td>
<td>148</td>
<td>203</td>
<td>148</td>
<td>203</td>
<td>148</td>
<td>203</td>
</tr>
<tr>
<td>Adjusted scores:</td>
<td>Site 1</td>
<td></td>
<td>Site 2</td>
<td></td>
<td></td>
<td>Both sites</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>As observed</td>
<td>95.13</td>
<td>93.82</td>
<td>As observed</td>
<td>93.51</td>
<td>91.52</td>
<td>As observed</td>
<td>93.35</td>
<td>93.02</td>
<td>As observed</td>
<td>94.35</td>
<td>93.02</td>
<td>As observed</td>
</tr>
<tr>
<td>N</td>
<td>105</td>
<td>97</td>
<td>98</td>
<td>98</td>
<td>98</td>
<td>98</td>
<td>203</td>
<td>148</td>
<td>203</td>
<td>148</td>
<td>203</td>
<td>148</td>
<td>203</td>
</tr>
</tbody>
</table>

*Full model: estimated net effects (positive favours intervention) confidence intervals & significance levels

| Intervention | -0.319 (-2.388, 1.750) | -1.158 (-3.235, 0.919) | -0.089 (-1.606, 1.428) | -0.003 (-0.026, 0.021) | -0.353 (-0.861, 0.155) |
| P            | 0.762 | 0.144 | 0.274 | 0.908 | 0.173 |
| Site         | 0.408 (-1.657, 2.474) | -0.927 (-3.010, 1.157) | 0.299 (-1.233, 1.820) | -0.001 (-0.025, 0.023) | -0.095 (-0.605, 0.415) |
| P            | 0.698 | 0.082 | 0.382 | 0.700 | 0.174 |

**Note**
All scores range from 0 to 100, with higher scores showing better outcomes.

*Shaded cells display full model in response to reviewers’ requests.

**Summary**
No significant differences between groups or sites.
Table 7 shows no significant differences between groups or sites in patient-reported generic and fall-specific quality of life or quality of care at either or both sites.

### Table 8: Self-reported falls within 30 days by group

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=236)</th>
<th>Control (n=175)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No falls</td>
<td>101 (43%)</td>
<td>63 (36%)</td>
</tr>
<tr>
<td>At least one fall</td>
<td>135 (57%)</td>
<td>112 (64%)</td>
</tr>
</tbody>
</table>

Table 8 shows that slightly fewer intervention group participants reported at least one subsequent fall within 30 days; the difference was 7% with a 95% CI from -17% to +3%.

### Table 9: Operational indicators by group and site

<table>
<thead>
<tr>
<th>Observed times</th>
<th>Job cycle time (minutes) [n = 436 I &amp; 343 C]</th>
<th>Emergency episode duration (minutes) [n = 436 I &amp; 343 C]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>90.03</td>
<td>279.08</td>
</tr>
<tr>
<td>SD</td>
<td>51.61</td>
<td>243.95</td>
</tr>
<tr>
<td>N</td>
<td>235</td>
<td>207</td>
</tr>
<tr>
<td>Site 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>92.22</td>
<td>155.07</td>
</tr>
<tr>
<td>SD</td>
<td>36.64</td>
<td>117.46</td>
</tr>
<tr>
<td>N</td>
<td>201</td>
<td>151</td>
</tr>
<tr>
<td>Combined</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>91.04</td>
<td>226.78</td>
</tr>
<tr>
<td>SD</td>
<td>45.29</td>
<td>216.27</td>
</tr>
<tr>
<td>N</td>
<td>436</td>
<td>358</td>
</tr>
<tr>
<td>Intervention effect</td>
<td>8.56 (2.18, 14.93); P=0.009</td>
<td>-5.68 (-38.54, 27.17); P=0.734</td>
</tr>
<tr>
<td>Site effect</td>
<td>0 because not significant*</td>
<td>130.1 (96.6, 163.5); P&lt;0.001</td>
</tr>
<tr>
<td>Significant covariates:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjusted times</td>
<td>Out of hours (P=0.001)</td>
<td>None</td>
</tr>
<tr>
<td>Site 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>91.04</td>
<td>As observed</td>
</tr>
<tr>
<td>SD</td>
<td>50.50</td>
<td>As observed</td>
</tr>
<tr>
<td>N</td>
<td>227</td>
<td></td>
</tr>
<tr>
<td>Site 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>90.36</td>
<td>As observed</td>
</tr>
<tr>
<td>SD</td>
<td>36.93</td>
<td>As observed</td>
</tr>
<tr>
<td>N</td>
<td>197</td>
<td></td>
</tr>
<tr>
<td>Combined</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>90.72</td>
<td>As observed</td>
</tr>
<tr>
<td>SD</td>
<td>44.66</td>
<td>As observed</td>
</tr>
<tr>
<td>N</td>
<td>424</td>
<td></td>
</tr>
</tbody>
</table>

*Full model: estimated effects (+ve: intervention higher), confidence intervals & significance levels

| Intervention effect | 17.07 (6.71, 27.43) P=0.001 | 2.81 (-49.97, 55.60) P=0.917 |
| Site effect         | 13.24 (3.04,23.47) P=0.011    | 137.90 (87.25, 188.54) P<0.001 |
| Interaction effect  | -12.56 (-25.75, 0.64); P=0.062 | -13.88 (-81.35, 53.59) P=0.686 |

*Shaded cells display full model in response to reviewers' requests; for job cycle time alone our staged analytical strategy needed 3 steps: 1st the full model with insignificant interaction; 2nd intermediate step with intervention effect = 9.33 (CI=2.91, 15.76; P=0.004) & site effect = 5.74 (CI=-0.74, 12.22; P=0.083); & 3rd the simple model under observed times with intervention effect alone.
The ‘parsimonious’ interpretation of Table 9 is that emergency ambulances were engaged for nine minutes longer for intervention participants than for control participants. However this difference did not translate into a significant difference in the duration of the complete emergency episode.

**Table 10: Compliance with protocols – documentation of key physiological indicators at scene**

<table>
<thead>
<tr>
<th></th>
<th>Intervention group (n=436)</th>
<th>Control group (n=343)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory rate</td>
<td>397 (91%)</td>
<td>323 (94%)</td>
</tr>
<tr>
<td>Pulse rate</td>
<td>414 (95%)</td>
<td>329 (96%)</td>
</tr>
<tr>
<td>Level of consciousness</td>
<td>405 (93%)</td>
<td>337 (98%)</td>
</tr>
</tbody>
</table>

Table 10 shows that the clinical documentation completed by attending paramedics was of a uniformly high standard; in particular it did not vary significantly between groups.

**Secondary analyses – patterns of CCDS usage and analysis by treatment received**

Tables 11 and 12 show that the reported use of CCDS varied widely between individual intervention paramedics, who used it between 0 and 22 times.

**Table 11: Number of times paramedics used CCDS**

<table>
<thead>
<tr>
<th>Frequency of CCDS use</th>
<th>Site 1 (n=9)</th>
<th>Site 2 (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>6 (67%)</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td>1</td>
<td>2 (22%)</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>1 (11%)</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td>5 or more</td>
<td>0</td>
<td>4 (50%)</td>
</tr>
</tbody>
</table>

**Table 12: Percentage of times paramedics used CCDS when attending patients**

<table>
<thead>
<tr>
<th>Percentage of participants for whom CCDS was used</th>
<th>Site 1 (n=9)</th>
<th>Site 2 (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>6 (67%)</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td>1% to 10%</td>
<td>3 (14%)</td>
<td>1 (12.5%)</td>
</tr>
<tr>
<td>11% to 20%</td>
<td>0</td>
<td>2 (25%)</td>
</tr>
<tr>
<td>21% to 30%</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>31% to 40%</td>
<td>0</td>
<td>2 (25%)</td>
</tr>
<tr>
<td>41% or more*</td>
<td>0</td>
<td>2 (25%)</td>
</tr>
</tbody>
</table>

* The maximum was by a paramedic who used CCDS for 47% of his participants

No clear predictors were identified for CCDS use in either site (Table 13).

**Table 13: Patient characteristics by CCDS use**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Site 1</th>
<th>Site 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CCDS used (n=5)</td>
<td>CCDS not used (n=230)</td>
</tr>
<tr>
<td>Men</td>
<td>2(40%)</td>
<td>75(33%)</td>
</tr>
<tr>
<td>Women</td>
<td>3(60%)</td>
<td>155(67%)</td>
</tr>
<tr>
<td>Mean age</td>
<td>84.4</td>
<td>82.0</td>
</tr>
<tr>
<td>Distance to nearest ED (miles)</td>
<td>12.2</td>
<td>6.9</td>
</tr>
</tbody>
</table>
In practice the use of the CCDS was associated with significantly higher rates of non-conveyance and referral to falls services (Table 14).

**Table 14: Care pathway by CCDS use**

<table>
<thead>
<tr>
<th>Observed frequencies</th>
<th>Not conveyed</th>
<th>Referral to falls service</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Site 1</td>
<td>3/5 (60%)</td>
<td>146/455 (32%)</td>
</tr>
<tr>
<td>Site 2</td>
<td>32/49 (65%)</td>
<td>128/270 (47%)</td>
</tr>
<tr>
<td>Both sites</td>
<td>35/54 (65%)</td>
<td>274/725 (38%)</td>
</tr>
<tr>
<td>Relative risk for CCDS use (95% CI), significance level</td>
<td>2.088 (1.107, 3.940) P=0.023</td>
<td>3.109 (1.403, 6.888) P=0.005</td>
</tr>
<tr>
<td>Relative risk for Site (95% CI), significance level</td>
<td>0.524 (0.385, 0.714), P&lt;0.001</td>
<td>0.598 (0.331, 1.082) P=0.089</td>
</tr>
<tr>
<td>Relative risk for interaction between CDSS and Site (95% CI), significance level</td>
<td>1.520 (0.225, 10.253), P=0.667</td>
<td>1.444 (0.135, 15.05) P=0.761</td>
</tr>
</tbody>
</table>

Table 15 shows that use of CCDS increased mean job cycle time by 10.9 minutes (95% CI from 0.5 to 21.4), although the time added was longer at site 1, where the CCDS was less frequently used. It also reduced the episode of emergency care (including ED attendance) by 113.8 minutes (95% CI from 77.2 to 150.3), although this effect was less marked at site 2.

**Table 15: Operational indicators by CCDS**

<table>
<thead>
<tr>
<th>Operational indicators</th>
<th>Site 1</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CCDS</td>
<td>Site 1</td>
<td>CCDS</td>
<td>Site 2</td>
</tr>
<tr>
<td>Mean job cycle time</td>
<td>107.38</td>
<td>87.14</td>
<td>95.54</td>
<td>83.26</td>
</tr>
<tr>
<td>(minutes)</td>
<td>(n=5)</td>
<td>(n=455)</td>
<td>(n=49)</td>
<td>(n=270)</td>
</tr>
<tr>
<td>Mean episode of</td>
<td>150.55</td>
<td>287.71</td>
<td>124.15</td>
<td>159.23</td>
</tr>
<tr>
<td>emergency care time</td>
<td>(n=4)</td>
<td>(n=390)</td>
<td>(n = 39)</td>
<td>(n = 218)</td>
</tr>
<tr>
<td>(minutes)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 16 shows that clinical documentation of key indicators of patient condition at scene, already known to be high, did not vary according to whether CCDS was reported.

**Table 16: Compliance with protocols – documentation of key physiological indicators at scene by CCDS reported usage**

<table>
<thead>
<tr>
<th></th>
<th>CCDS used (n=54)</th>
<th>CCDS not used (n=725)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory rate</td>
<td>47 (87%)</td>
<td>673 (93%)</td>
</tr>
<tr>
<td>Pulse rate</td>
<td>53 (98%)</td>
<td>690 (95%)</td>
</tr>
<tr>
<td>Level of consciousness</td>
<td>48 (89%)</td>
<td>694 (96%)</td>
</tr>
</tbody>
</table>

**Adverse events**

We initiated the procedure for investigating a Suspected Unexpected Serious Adverse Reaction (SUSAR) only once – following the death of a trial participant left at home by the attending crew with a referral to the falls service. The research team remain blind to the details, including the random allocation. Following a report from the ambulance service principal investigator (RW), DMEC and TSC chairs agreed no further action was required.
Discussion

Strengths and weaknesses

Our interpretation of trial findings suffers from three main limitations: the erratic use of the health technology; the quality of some operational data; and the foreshortening of the follow-up period following the resolution of major problems in implementing the technology.

CCDS usage was low in both sites, although reported usage was higher in site 2, where paramedics were already using the hardware for clinical documentation related to patient condition and care. One paramedic did not receive the hardware or training to use the CCDS and was therefore unable to use the technology but remained in the intervention group for ‘analysis by treatment allocated’. This reflects the pragmatic nature of the trial, as this might be expected in real life if the intervention were implemented.

Some aspects of data quality affect the reliability of trial findings. We suspect that data retrieval was incomplete at site 1 and that data about usage of the CCDS were lost. ED, inpatient and mortality outcomes were incomplete, through both the anonymised and patient-identifiable routes, owing to patients not being matched to central registers and a lag to the availability of routine health data. Fortunately the cumulative nature of our primary outcome, and the manual searching of 999 records for subsequent events, means that a primary outcome was available for all study participants. Furthermore we avoided the danger of selection bias caused by crews classifying calls differently in different arms of the trial; for example crews might be reluctant to code a case as a fall because that would mean they should use the CCDS. Instead we identified potential participants from 999 records. We then found that there was an excellent match between calls coded as a fall by ambulance dispatchers and crews. Although using this method meant that a few calls were included that were probably not related to a fall, we were confident that the distribution of falls and non-falls was the same in both groups.

Implementation of the randomised trial, always challenging in emergency pre-hospital care, was generally successful. However delays in implementing the intervention affected our ability to collect the planned 6-month outcomes within the funded trial period. Nevertheless we came close to our revised sample size.

Falls services do not offer a crisis intervention, but a longer term multi-disciplinary, multi-faceted assessment and package of tailored care [13]. Although the one month outcome might detect important differences in short term emergency contacts, with the potential to highlight safety concerns associated with changed practice, effects on quality of life and further falls would be unlikely to show up at this early stage. Trial commissioners and the external TSC agreed that, despite the reduced sample size and loss of the 6 months follow up, the study could valuable data about effects on the processes of care, as well as about barriers and facilitators to implementation (reported in chapter 6). Following the theoretical underpinning for the study, we therefore placed a higher emphasis on the key process that would need to change in order to achieve improved outcomes for patients – the referral rate to falls services.

Generalisability

The SAFER 1 trial was undertaken at two UK ambulance service sites, with the same CCDS implemented at each site. Patient recruitment reached a level that gives us confidence that we would have detected an effect on our original primary outcome of subsequent emergencies. However, the CCDS was implemented in different ways at each site and was not fully integrated with the electronic data capture system at either site. This dependence on local conditions related to IT implementation may limit the applicability of findings to other settings.
**Interpretation**

In this trial we found no effect on our original primary outcome—time to subsequent emergency contact or death—for a fall or for any reason; or patient-reported outcomes—quality of life (generic or fall related), satisfaction with care.

However, and despite low reported usage of the CCDS, we found a significant effect on referral rates to falls services, with the rate twice as high in patients attended by intervention group paramedics as in those attended by paramedics in the control group. This effect was seen more widely than in those when the health technology was reported to have been used, suggesting that this complex intervention affected practice generally, perhaps through a learned effect from the training or usage of the technology. It has previously been found that decision making is complex in prehospital emergency care [31]. Although the PPOPS study reported a change in processes and outcomes of care indicating effectiveness of paramedic practitioners [16], studies of paramedic interventions have often found difficulty in achieving real change in practice [32,33]. It has previously been found that crews have used protocols to justify current practice rather than to support decisions: they make the decision to leave the patient at home and then use the protocol to back up this decision—or to “cover their backs” [25,26].

Operational process indicators showed that 999 job cycle time was increased for patients attended by paramedics in the intervention group, and particularly when the CCDS was reported to have been used. Some of this impact on time may have been due to usability problems or lack of familiarity, reinforced by infrequent usage. Some of these problems were related to the introduction, at site 1, of an entire electronic data capture system (ePRF), and others might be resolved with improved integration of ePRF and CCDS software. However, the increased time spent in the prehospital phase may be offset by some avoided journeys and time spent in the ED, as the episode of emergency care was not lengthened in the intervention group.

With the low usage found in this trial, and the likely timescale for detecting effects of the referral to the falls service, we could not have expected to have found any effects on our original primary outcome of emergency healthcare contacts, deaths or patient reported outcomes at 1 month. However, findings related to changed practice which resulted in a doubling of referrals to falls services provide preliminary evidence that it is worth supporting the further development and evaluation of CCDS in an integrated and user friendly format.

**Other Information**

**Registration**

Trial Registration: ISRCTN10538608
References


30. Halter M, et al. Fit to be left: can ambulance staff use an assessment tool to decide if an older person who has fallen can be safely left at home? 2005, London Ambulance Service NHS Trust London


Chapter 5 Cost-effectiveness of Computerised Clinical Decision Support for emergency ambulance personnel

Abstract

**Aims**

To assess the cost-effectiveness of the SAFER 1 intervention Computerised Clinical Decision Support (CCDS) software on hand held computers – in helping paramedics to decide whether older people who had suffered a fall need to attend hospital or stay at home with referral to community falls services. In particular to estimate the effect of the intervention within 30 days on: hospital emergency care; inpatient stays; subsequent 999 calls; subsequent emergency care; subsequent inpatient stays; and referrals to falls services from the perspective of emergency care within the UK NHS.

**Setting**

Two Ambulance Services within which we successfully randomised 17 paramedics to the intervention arm and 17 to the control.

**Participants**

Eligible patients aged 65 or over were the subjects of emergency ambulance calls categorised by the call-taker as a fall without priority symptoms, who were attended by a trial paramedic during the recruitment period while living in the catchment area of a falls service but not in residential care. Those who did not opt out were sent a follow-up questionnaire one month after the initial 999 call to collect information on their care after the initial call, their fear of falling, their perceived quality of care and their health-related quality of life.

**Results**

In Site 1 we recruited 460 people and 319 in Site 2 area. Randomisation of paramedics allocated 436 participants to the intervention and 343 to usual care. The main effect of the intervention was to double the referral rate to community falls services – from 5% to 10%.

We estimated the mean cost of implementing the CCDS intervention as £154 per patient recruited; and that of emergency health care as £2981 in the intervention group and £2567 in the control group. Though not itself significant (p = 0.22), this difference includes a significant difference in the cost of referrals to falls services (p = 0.014). Thus over 30 days, the costs of the SAFER 1 intervention were not offset by reductions in emergency health care use or improved health-related quality of life. However limiting follow-up to 30 days omits the medium- and long-term effects of the intervention, notably referrals to falls services. So our analysis could not detect any of the benefits of this pathway.

Fortunately Logan’s concurrent randomised trial to evaluate referrals to falls services found major improvements in the numbers of falls and fall-related ambulance trips per person over 12 months, and scores on the Nottingham Index of Activities of Daily Living and the Falls Efficacy Scale. Hence the doubling of falls referrals in SAFER 1 at a cost of £154 per patient, coupled with Logan’s positive findings on falls service referrals, is more promising. We are therefore constructing an economic model to quantify this inference.

**Conclusions**

The statistically significant doubling of referrals to falls services, and the intervention cost of only £154 per patient, suggest that CCDS has the potential to yield value for money. Hence more research is needed to evaluate CCDS definitively, notably with a longer follow-up period to study changes in quality of life and the costs of falls services.
**Introduction**

Demand for immediate care through the emergency ambulance service is increasing across the UK and internationally. However as up to half of all callers have no clinical need to attend an emergency department (ED) and are left at home, a community-based response may often be more appropriate than hospital attendance. Though health policy in the UK encourages ambulance services to offer alternative services to such callers, there is little evidence about the safety and effectiveness of new models of care. Alongside training and referral pathways, handheld devices with decision support software could improve the care of this vulnerable patient group. Most people who fall do not seek medical advice [1,2] but older people still account for between 12 and 21% of ED visits. Although prevention strategies are effective [3], reduction of falls, injuries and associated morbidity depend on early identification of people at high risk and delivery of interventions across traditional service boundaries [4]. The Support and Assessment for Fall Emergency Referral (SAFER 1) trial therefore assessed the costs and benefits of a new healthcare technology - hand-held computers with Computerised Clinical Decision Support (CCDS) software to help paramedics decide who needs hospital attendance, and who can be safely left at home with referral to community falls services.

The study was a pragmatic cluster randomised trial with a qualitative component [5]. The evaluated intervention comprised paramedic training and CCDS software on a hand-held tablet Personal Computer (PC) to help ambulance paramedics attending patients decide who to take to hospital and who to leave at home with referral to a community falls service.

The aims of this study were to estimate the effect of the intervention on the costs within 30 days of: hospital emergency care, inpatient stays, subsequent 999 calls, subsequent emergency care, subsequent inpatient stays and referrals to falls services; and thus to assess the cost-effectiveness of the CCDS in helping paramedics to decide who needs hospital attendance, and who can be safely left at home with referral to falls services. The study originally planned to estimate the effect of the intervention on consultations with general practitioners, district nurses, social workers and nursing or residential care. However data on these services, especially residential care, the largest component, were not reliable enough to cost resource use with confidence. Hence we adopted the narrower perspective of emergency care and its sequelae in the UK NHS.

**Methods**

**Recruitment**

**Ambulance Trusts**

Two UK ambulance services finally contributed to the study. We recruited and randomised a total of 42 paramedics, and trained half in the intervention. Eight paramedics withdrew from the study, leaving 17 paramedics randomised to the intervention and 17 to the control.

Eligible patients aged 65 or over were the subject of an emergency ambulance call categorised by the call-taker as a fall without priority symptoms, attended by a trial paramedic during the recruitment period, living in the catchment area of a falls service but not living in residential care. Eligible patients were provisionally included in the study then offered an opportunity to opt out. Participating patients received questionnaires approximately one month after their index fall. We also tracked them through the emergency ambulance system, ED departments, GPs and coroners to identify further contacts with these services (or death) within one month. In addition, diagnostic codes for each contact were collected.

**Patient recruitment**

Over the course of the trial, 608 patients from the intervention group and 461 from the control group were deemed ineligible as they did not meet inclusion criteria, or had insufficient information to confirm eligibility [e.g. no Patient Clinical Record (PCR)], or refused to be contacted, or opted out of the study. All eligible patients were followed up 30 days later with a
questionnaire. In total, there were 1044 potentially eligible patients seen by the intervention ambulance paramedics, and 804 seen by the control paramedics.

Data collection
In Site 1 routine clinical data, including clinical diagnoses, treatments and clinical outcomes relating to participants’ initial ED attendances and hospital stays and subsequent ED attendances and hospital stays came from Swansea University’s SAIL database (or PCRs where no electronic data were available). In Site 2 data relating to the initial 999 call and subsequent 999 calls were collected from PCRs; and data relating to ED attendances and hospital stays were obtained from clinical records at the hospitals treating the patients. The questionnaires one month after the initial 999 call measured health-related quality of life with the SF12v1 [6], fear of falling through the Modified Falls Efficacy Scale [7], patient satisfaction using the Quality of Care Monitor [8], self-reported falls after the index fall and subsequent contacts with health services. The SF-6D [9] utility score, derived from six questions within the SF-12v2, estimated the quality-adjusted life years (QALYs) gained from the intervention [6].

Costs
In costing health technology it is important to distinguish between the direct costs of setting up and implementing the technology and the indirect costs arising from changes in resource use as a result of the technology being implemented. We estimated the direct costs of the CCDS following discussions with the software and hardware developers and the SAFER 1 trial team. We based them on the costs of time used by trainer and trainees, for example the cost of overtime by paramedic on their day off.

We estimated the costs of health care by multiplying resource use by published unit costs. Resource use data collected for the economic evaluation were: initial ambulance attendances; subsequent ambulance attendances; initial ED attendances; subsequent ED attendances; initial inpatient stays; subsequent inpatient stays and referrals to falls services. We collected these data from routine data available in the SAIL database, paper records provided by the East of England Ambulance Service, paramedic records, routine hospital records and patient-completed questionnaires. We derived resource use in nursing homes and residential homes from the follow-up questionnaires. Unit costs at 2009-10 prices for these resources came from NHS Reference Costs [10] (Table 1). However we did not include the costs of episodes of care outside the 30-day follow up in the analysis.

Table 1: NHS unit costs

<table>
<thead>
<tr>
<th>Health Service Resource</th>
<th>Unit Cost (£)</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial ambulance attendance (conveyed)</td>
<td>246</td>
<td>NHS Reference Costs</td>
</tr>
<tr>
<td>Initial ambulance attendance (not conveyed)</td>
<td>225</td>
<td>NHS Reference Costs</td>
</tr>
<tr>
<td>Subsequent ambulance attendance (conveyed)</td>
<td>246</td>
<td>NHS Reference Costs</td>
</tr>
<tr>
<td>Subsequent ambulance attendance (not conveyed)</td>
<td>225</td>
<td>NHS Reference Costs</td>
</tr>
<tr>
<td>Initial ED attendance</td>
<td>427 a</td>
<td>NHS Reference Costs</td>
</tr>
<tr>
<td>Subsequent ED attendance</td>
<td>427 a</td>
<td>NHS Reference Costs</td>
</tr>
<tr>
<td>Initial inpatient stay</td>
<td>237-433</td>
<td>NHS Reference Costs</td>
</tr>
<tr>
<td>Subsequent inpatient stay</td>
<td>234-414</td>
<td>NHS Reference Costs</td>
</tr>
<tr>
<td>Falls service referrals</td>
<td>77</td>
<td>NHS Reference Costs</td>
</tr>
</tbody>
</table>

a 427 is the mean of the three national average unit costs for ED attendances
Outcomes
The primary outcomes for the cost-effectiveness analysis were the effects within 30 days of the intervention on quality of life, hospital emergency care, inpatient stays, subsequent 999 calls, subsequent emergency care, subsequent inpatient stays, and referrals to falls services. We obtained the resource data from Patient Clinical Records (PCRs) and electronic Patient Report Forms (ePRFs) completed by paramedics. We derived SF-6D quality of life scores from SF-12 responses at 30 days, and estimated QALYs by assuming that both groups had the same utility scores at baseline.

We used one-way sensitivity analyses to assess the robustness of the results to changes in the model parameters and probabilistic sensitivity analysis to assess the extent to which the intervention could be regarded as representing value for money relative to the use of funds elsewhere [11,12].

Results
There were 779 participants – 460 from site 1 and 319 from site 2. The mean age across both sites was 82. Of these 436 patients were randomised to the intervention group (of whom 65% were female) and 343 to the control group (of whom 61% were female).

Implementation costs across sites
The mean cost of the SAFER 1 intervention - across both ambulance services - was estimated as £154, including training costs for paramedics, IT support for the CCDS software and clinical support (Table 2).

| Table 2: Costs associated with implementation of SAFER 1 intervention |
|---------------------------------|-----------------|-----------------|
| Project Manager                 | 13,000          | 12,000          |
| ICT Support                     | 2,500           | 2,000           |
| Training costs                  | 1,700           | 1,500           |
| Clinical Support                | 2,645           | 800             |
| Testing firewalls (PEN Test)    | 2,438           | 2,438           |
| Decision Support Software Licence | 198             | 198             |
| Hands on Training Face to Face  | 4,478           | 4,478           |
| Engineering Work                | 3,483           | 3,483           |
| Consultancy                     | 4,975           | 4,975           |
|                                 | 35,417          | 31,872          |
| Total                           | 67,288          |
| Mean cost per patient (n = 436) | 154             |

Resource use
Costs of health care use by participants following care by trial paramedics were estimated by multiplying resource use by published unit costs. Table 3 shows that the mean health care cost was £2981 in the intervention group and £2567 in the control group (p = 0.225). The cost of initial hospital stays (£1053 and £926 respectively; p = 0.510) and subsequent hospital stays (£1138 and £1001 respectively; p = 0.606) were the major cost drivers. The mean length of stay for both initial and subsequent hospital episodes was the same across both arms. However there was a statistically significant difference in the cost of referrals to the falls...
service – with 42 patients (10%) out of 436 patients referred in the intervention group compared with 17 (5%) out of 343 in the control group ($p = 0.014$).

Table 3: Resource use

<table>
<thead>
<tr>
<th></th>
<th>Intervention No. of Instances</th>
<th>Intervention Mean £ (n = 436)</th>
<th>Intervention SD £</th>
<th>Intervention mean stay (days)</th>
<th>Control No. of Instances</th>
<th>Control Mean £ (n = 343)</th>
<th>Control SD £</th>
<th>Control mean stay</th>
<th>Mean Difference (95% CI)</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial 999 call</td>
<td>436</td>
<td>237</td>
<td>10</td>
<td>-</td>
<td>343</td>
<td>239</td>
<td>10</td>
<td>-</td>
<td>-1 (-3, 0)</td>
<td>0.138</td>
</tr>
<tr>
<td>Initial ED Attendance</td>
<td>233</td>
<td>228</td>
<td>213</td>
<td>-</td>
<td>217</td>
<td>249</td>
<td>211</td>
<td>-</td>
<td>-21 (-51, 9)</td>
<td>0.175</td>
</tr>
<tr>
<td>Initial Hospital stay</td>
<td>127</td>
<td>1,053</td>
<td>2,741</td>
<td>4</td>
<td>84</td>
<td>926</td>
<td>2,535</td>
<td>4</td>
<td>126 (-250, 502)</td>
<td>0.510</td>
</tr>
<tr>
<td>Subsequent 999 calls</td>
<td>175</td>
<td>93</td>
<td>232</td>
<td>-</td>
<td>128</td>
<td>86</td>
<td>214</td>
<td>-</td>
<td>7 (-25, 39)</td>
<td>0.665</td>
</tr>
<tr>
<td>Subsequent ED Attendance</td>
<td>72</td>
<td>71</td>
<td>188</td>
<td>-</td>
<td>50</td>
<td>62</td>
<td>183</td>
<td>-</td>
<td>8 (-18, 35)</td>
<td>0.537</td>
</tr>
<tr>
<td>Subsequent Hospital stay</td>
<td>92</td>
<td>1,138</td>
<td>3,763</td>
<td>5</td>
<td>81</td>
<td>1,001</td>
<td>3,550</td>
<td>4</td>
<td>137 (-383, 657)</td>
<td>0.606</td>
</tr>
<tr>
<td>Falls service referrals</td>
<td>42</td>
<td>7</td>
<td>23</td>
<td>-</td>
<td>17</td>
<td>4</td>
<td>17</td>
<td>-</td>
<td>4 (1, 6)</td>
<td>0.014</td>
</tr>
<tr>
<td>Total costs</td>
<td>-</td>
<td>2,981</td>
<td>4,851</td>
<td>-</td>
<td>-</td>
<td>2,567</td>
<td>4,564</td>
<td>-</td>
<td>414 (-256, 1084)</td>
<td>0.225</td>
</tr>
</tbody>
</table>

We undertook sensitivity analysis restricted to resources used specifically for subsequent falls. Table 4 shows the cost difference in the same areas as in Table 3. There was a statistically significant difference in initial ED attendances ($p = 0.010$) with mean intervention costs of £75 compared with £47 in the control arm. However the net difference in fall-related costs was only £52 greater in the intervention group with a wide confidence interval.

Table 4: Resource use (Fall Related)

<table>
<thead>
<tr>
<th></th>
<th>Intervention No. of Instances</th>
<th>Intervention Mean £ (n = 436)</th>
<th>Intervention SD £</th>
<th>Intervention Mean length of stay in hospital (days)</th>
<th>Control No. of Instances</th>
<th>Control Mean £ (n = 343)</th>
<th>Control SD £</th>
<th>Control Mean length of stay in hospital (days)</th>
<th>Mean Difference (95% CI of the Difference)</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial 999 call</td>
<td>436</td>
<td>237</td>
<td>10</td>
<td>-</td>
<td>343</td>
<td>238</td>
<td>10</td>
<td>-</td>
<td>-1 (-3, 0)</td>
<td>0.138</td>
</tr>
<tr>
<td>Initial Fall Related ED Attendance</td>
<td>77</td>
<td>75</td>
<td>163</td>
<td>-</td>
<td>38</td>
<td>47</td>
<td>134</td>
<td>-</td>
<td>28 (7, 50)</td>
<td>0.010</td>
</tr>
<tr>
<td>Initial Fall Related Hospital stay</td>
<td>57</td>
<td>355</td>
<td>1,282</td>
<td>11</td>
<td>43</td>
<td>409</td>
<td>1,381</td>
<td>14</td>
<td>-55 (-243, 133)</td>
<td>0.568</td>
</tr>
<tr>
<td>Fall Related Subsequent 999 calls</td>
<td>68</td>
<td>42</td>
<td>141</td>
<td>-</td>
<td>43</td>
<td>34</td>
<td>123</td>
<td>-</td>
<td>8 (10, -11)</td>
<td>0.434</td>
</tr>
<tr>
<td>Falls Related Subsequent ED Attendance</td>
<td>25</td>
<td>24</td>
<td>99</td>
<td>-</td>
<td>16</td>
<td>20</td>
<td>90</td>
<td>-</td>
<td>5 (-9, 18)</td>
<td>0.508</td>
</tr>
<tr>
<td>Falls Related Subsequent Hospital stay</td>
<td>40</td>
<td>497</td>
<td>2,590</td>
<td>31</td>
<td>36</td>
<td>582</td>
<td>3,004</td>
<td>27</td>
<td>-86 (-480, 308)</td>
<td>0.669</td>
</tr>
<tr>
<td>Falls service referrals</td>
<td>42</td>
<td>7</td>
<td>23</td>
<td>-</td>
<td>17</td>
<td>4</td>
<td>17</td>
<td>-</td>
<td>4 (1, 6)</td>
<td>0.014</td>
</tr>
<tr>
<td>Total Falls Related costs</td>
<td>-</td>
<td>1,385</td>
<td>3,031</td>
<td>-</td>
<td>-</td>
<td>1,333</td>
<td>3,559</td>
<td>-</td>
<td>51 (-413, 515)</td>
<td>0.828</td>
</tr>
</tbody>
</table>
Health-related quality of life
We estimated SF-6D utilities from the 30-day questionnaire responses. However missing data rates were high with 62% missing for both control and intervention groups. To increase the response rate for estimating the SF-6D, we therefore imputed missing data by the SPSS 'maximum likelihood' algorithm when patients had answered six or more items from the SF-12. This decreased the missing data rates to 49% and 50% for control and intervention groups respectively. The mean utility scores were then higher at 30 days in the control group, although the differences were not statistically significant.

Table 5: SF-6D Results

<table>
<thead>
<tr>
<th></th>
<th>Intervention Mean n = 165</th>
<th>Control Mean n = 131</th>
<th>Mean difference (95% CI of the difference)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-6D (No imputation)</td>
<td>0.560</td>
<td>0.570</td>
<td>-0.01 (- 0.04, 0.02)</td>
</tr>
<tr>
<td>QALY over 30 days</td>
<td>0.014</td>
<td>0.015</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention Mean n = 219</td>
<td>0.570</td>
<td>0.550</td>
<td>Mean difference (95% CI of the difference)</td>
</tr>
<tr>
<td>QALY over 30 days</td>
<td>0.018</td>
<td>0.021</td>
<td></td>
</tr>
</tbody>
</table>

Cost-effectiveness analysis
The mean difference in costs (Table 3) and QALYs (Table 5) between groups at 30 days resulted in an Incremental Cost Effectiveness Ratio (ICER) of minus £41,628 without imputation and minus £25,785 per QALY when we imputed as many utilities as we could. These negative ICERs indicate that the intervention cost is not offset by reductions in resource use over 30 days so that there is a net cost of CCDS; however there is no compensating utility gain at 30 days, indeed a small loss. In short the CCDS intervention is 'dominated' by usual practice up to 30 days.
Sensitivity Analysis

A series of sensitivity analyses examined changes in cost per QALY by combining the best and worst limits of estimated confidence intervals and varying costs for implementing the intervention by plus or minus 30% (Table 6).

Table 6: Sensitivity Analysis

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Cost of CCDS (£)</th>
<th>Incremental cost of health care (£)</th>
<th>Incremental SF-6D utility</th>
<th>£ / imputed QALY (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline cost of SAFER 1 intervention</td>
<td>154</td>
<td>414 (95% CI: -740, 1568)</td>
<td>-0.02 (-0.05, 0.02)</td>
<td>-25,785</td>
</tr>
<tr>
<td>Worse cost difference</td>
<td>1568</td>
<td>0.02</td>
<td>+78,400</td>
<td></td>
</tr>
<tr>
<td>Best effect difference</td>
<td>1568</td>
<td>-0.05</td>
<td>`31,360'</td>
<td></td>
</tr>
<tr>
<td>Worse cost difference</td>
<td>1568</td>
<td>-0.05</td>
<td>`+14,800'</td>
<td></td>
</tr>
<tr>
<td>Best effect difference</td>
<td>1568</td>
<td>-0.05</td>
<td>`-37,000'</td>
<td></td>
</tr>
<tr>
<td>Reduce cost of CCDS intervention by 30%</td>
<td>108</td>
<td>368 (-786, 1522)</td>
<td>0.02</td>
<td>`22,920'</td>
</tr>
<tr>
<td>Increase cost of CCDS intervention by 30%</td>
<td>201</td>
<td>461 (-693, 1615)</td>
<td>0.02</td>
<td>`28,712'</td>
</tr>
</tbody>
</table>

To assess the chance that the CCDS intervention represents value for money, Figure 1 displays a cost-effectiveness acceptability curve (CEAC).

Figure 1: Cost-effectiveness acceptability curve for SAFER 1 intervention
The CEAC plots the probability that the CCDS yields value for money against the threshold that NHS decision-makers are willing to pay for an extra QALY. Throughout the range of thresholds recommended by the National Institute of Health & Clinical Excellence (NICE) (£20,000 to £30,000) this probability lies below 15%. Hence the CCDS intervention cannot be regarded as cost-effective relative to usual practice over 30 days.

We also estimated the cost of setting up the intervention in an ambulance service that has no ePRF and therefore incurs additional costs to use the CCDS technology. The estimates were based on the costs that Site 1 incurred in introducing the CCDS plus the costs of introducing the ePRF capability in 12 vehicles and amounted to £92,778 (Table 8).

We also estimated the annual running costs of the CCDS intervention in 12 vehicles with ePRF capability. If there were no new paramedics trained on the CCDS software and no extra SIM cards were needed, then the running costs associated with the SAFER 1 intervention would be virtually nil.

Table 7: Estimated set up and implementation costs for a Trust with no ePCR

<table>
<thead>
<tr>
<th></th>
<th>Based on 12 vehicles (5 RRVs) (£)</th>
<th>Based on 12 vehicles (including 5 RRVs) and annualised capital charges calculated using 3.5% annual discount rate and assuming equipment needs replacing every 3 years (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handheld Tablet</td>
<td>46,200</td>
<td>16,490</td>
</tr>
<tr>
<td>Printers and paper</td>
<td>7,212</td>
<td>2,621</td>
</tr>
<tr>
<td>Downtime of Vehicle (ambulance)</td>
<td>2,892</td>
<td>2,892</td>
</tr>
<tr>
<td>Downtime of Vehicle (RRV)</td>
<td>301</td>
<td>301</td>
</tr>
<tr>
<td>Chargers</td>
<td>300</td>
<td>107</td>
</tr>
<tr>
<td>Testing firewalls (PEN Test)</td>
<td>2,438</td>
<td>2,438</td>
</tr>
<tr>
<td>Decision Support Software Licence</td>
<td>198</td>
<td>198</td>
</tr>
<tr>
<td>GPRS Sim Cards (cost per month)</td>
<td>456</td>
<td>456</td>
</tr>
<tr>
<td>Training costs</td>
<td>1,700</td>
<td>1,700</td>
</tr>
<tr>
<td>Project Manager</td>
<td>13,000</td>
<td>13,000</td>
</tr>
<tr>
<td>ICT Support</td>
<td>2,500</td>
<td>2,500</td>
</tr>
<tr>
<td>Clinical Support</td>
<td>2,645</td>
<td>2,645</td>
</tr>
<tr>
<td>Hands on Training Face to Face</td>
<td>4,478</td>
<td>4,478</td>
</tr>
<tr>
<td>Engineering Work</td>
<td>3,483</td>
<td>3,483</td>
</tr>
<tr>
<td>Consultancy</td>
<td>4,975</td>
<td>4,975</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>92,778</strong></td>
<td><strong>58,284</strong></td>
</tr>
</tbody>
</table>
Discussion

Delays in implementing the CCDS beyond the control of the research team reduced the period of follow-up from six months to 30 days. Formally, therefore, the aims of this study were to estimate the cost of the intervention over 30 days covering: hospital emergency care, inpatient stays, subsequent 999 calls, subsequent emergency care, subsequent inpatient stays and referrals to falls services; and to assess the cost-effectiveness, again over 30 days, of the intervention in helping paramedics to decide who needs hospital attendance, and who can be safely left at home with referral to community falls services.

At first sight the findings show that it is highly unlikely that the intervention is cost-effective relative to current practice. However limiting follow-up to 30 days effectively prevented us from studying the medium- or long-term effects of the intervention. Yet one of the main pathways by which CCDS achieves benefits is by referrals to falls services, which take up to six weeks to respond, and even longer to yield benefits for those referred. Thus our formal analysis could not detect any of the putative benefits of this pathway.

Fortunately Logan et al (2010) conducted a randomised trial to evaluate referrals to community falls services [13]. They found major improvements in the numbers of falls and fall-related ambulance trips per person over 12 months and the median scores on the Nottingham Index of Activities of Daily Living and the Falls Efficacy Scale, but not the number or duration of hospital admissions (Table 5). Unfortunately they did not report the cost of the falls service or subsequent changes in resource use. Nevertheless the doubling of falls referrals in SAFER 1 at a cost of only £154 per patient, coupled with Logan’s positive findings on falls service referrals, is far more promising than our weak, formal economic analysis. We are therefore constructing an economic model to quantify this conclusion.

Table 8: Outcome Measures

<table>
<thead>
<tr>
<th>Outcome Measures</th>
<th>Control (n=102)</th>
<th>Intervention (n = 102)</th>
<th>Adjusted effect size (95% CI)</th>
<th>p value (&lt;0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate of falls per person-year</td>
<td>7.68</td>
<td>3.46</td>
<td>0.45 (0.35, 0.58)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total no. of times emergency ambulance called for a fall</td>
<td>365</td>
<td>245</td>
<td>0.60 (0.40, 0.92)</td>
<td>0.018</td>
</tr>
<tr>
<td>Total no. of hospital admissions</td>
<td>99</td>
<td>97</td>
<td>0.98 (0.69, 1.40)</td>
<td>0.93</td>
</tr>
<tr>
<td>Total no. of days in hospital in year</td>
<td>1141</td>
<td>1257</td>
<td>1.13 (0.60, 2.13)</td>
<td>0.70</td>
</tr>
<tr>
<td>Median Nottingham index of Activities of Daily Living (higher better)</td>
<td>6</td>
<td>8</td>
<td>3.47 (2.13, 4.81)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Median Falls Efficacy Scale score (lower better)</td>
<td>76</td>
<td>57</td>
<td>16.5 (9.8, 23.2)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Another important caveat to our formal economic analysis stems from the low usage of the intervention – only five times in Site 1 and 49 in Site 2. Hence, even though SAFER 1 achieved a significant increase in referrals to falls services, the effect on benefits and costs was minimal. Thus more research is needed to build on the promise suggested by the combination of SAFER 1 and Logan et al [13] and estimate the long-term cost-effectiveness of CCDS technology.

The main technical issue was which costs to include in assessing the intervention. The two ambulance services differed in the software available during the trial. Site 2 already had Electronic Patient Record Form (ePRF) software within the hand-held computers on their ambulances and RRVs. Thus they needed only to install the CCDS software on their computers. As Site 1 had neither system in their vehicles, however, they incurred extra costs in introducing the intervention, including the time needed to fit the equipment. These installation and implementation issues also affected how smoothly the trial ran.
Conclusion

The SAFER 1 intervention did not reduce emergency health care use, or improve health-related quality of life, within 30 days among patients randomised to the intervention group relative to those in the control group who received usual care. However it did double the rate of referrals to the community falls service at a cost of only £154 per intervention patient. Coupled with the known effectiveness of community falls services, this suggests that the SAFER 1 intervention has the potential to yield value for money. Hence more research is needed to evaluate this technology, especially over a longer period to permit internal study of the putative benefits of the CCDS on quality of life and the cost-effectiveness of the care pathway through falls services.
References


Chapter 6 Understanding how Computerised Clinical Decision Support for paramedics in the face-to-face assessment and care of older people who had suffered a fall was used and experienced by patients; paramedics and other stakeholders

Abstract

Objectives
The objectives of this qualitative study are to add meaning to the quantitative findings from the SAFER 1 trial through exploring the views and experiences of key participants in the trial, and identify the opportunities and challenges of using computerised clinical decision support (CCDS) in 999 ambulance settings in the UK to improve the quality and safety of patient care for elderly fallers.

Qualitative data collection
Semi-structured schedules (Appendix 6) to guide a combination of face-to-face interviews, telephone interviews and focus groups conducted at key points in the trial.

Participants
50 participants including patients, intervention group paramedics, and key stakeholders in the wider system from two ambulance service trust sites in the UK

Analyses
Deductive and inductive analyses according to the principles of ‘Framework’, a model for analysing qualitative data for applied policy research.

Results
Patients/carers: The analysis revealed a range of views about paramedics using CCDS. Some were supportive, some raised concerns about taking focus away from patient, and affecting a sense of confidence in the practitioner. There was a strong presumption that personal health data howsoever held was properly protected. No objections relating to the security of data held electronically were raised.

Paramedics: Before the trial began, the dominant view in the data was that participation in SAFER 1 offered paramedics developmental opportunities to receive training, improve their ability to do a good job - for the service and patients - and to provide better access to clinical information. Following the trial period, intervention paramedics reported varied experiences of use, largely depending on local factors including system configuration. The CCDS was associated with positive influences on how paramedics make decisions. Some advantages relating to electronic data capture, access to clinical guidelines, new pathways of care, and the potential to improve patient care and data transfer, were also evident. The main challenges to use related to hardware and non-integrated software, operational impact (time on scene), and reliability of organisational support.

Stakeholders: The use of the technology was seen to have substantial benefits for the service and for patients. Strategies associated with meeting the challenges of its implementation were improved communication, refining the CCDS software to be more user-friendly, resolution of logistical, connectivity and hardware issues, and the development of robust systems to maintain continuity of support. The main operational issues evident at both sites were balancing the need to meet existing standards, with developing new equipment and working
practices that may benefit patients and service providers in the future that require investment in training development.

**Conclusion:**

Despite the need to overcome organisational and operational challenges, the CCDS appears to be associated with changing how paramedics make their decisions about whether to convey older patients who may fall regularly to hospital or leave them at home with appropriate support, bringing potential advantages for patients, paramedics, the ambulance service and the wider system.
Introduction
The SAFER 1 trial was a pragmatic cluster randomised evaluation of a complex intervention that involved significant changes in how clinical staff in two emergency (999) ambulance settings in the UK recorded clinical patient information and made decisions at the point of patient contact [1]. The intervention consisted of training a group of paramedics in each of the participating sites to use Computerised Clinical Decision Support (CCDS). The CCDS was installed alongside electronic patient record (EPR) software, onto a tablet computer, to assist the paramedic to decide whether an older person receiving a 999 response following a fall, could be left at home safely or needed to be conveyed to hospital. The control group paramedics in the same sites followed their usual practice. Qualitative approaches have been found to be particularly useful in understanding the processes of cultural and organisational changes associated with complex interventions in health and social care that cannot be captured using quantitative methods alone [2,3]. Alongside the quantitative comparison of costs, processes and outcomes of care in the SAFER 1 trial we therefore conducted a qualitative study to explore different perspectives of using CCDS in an emergency ambulance service setting.

Aims and objectives
The overall aims of the qualitative element of the trial were to better understand the processes and perceived impact of CCDS, and add meaning to quantitative findings through exploring the views and experiences of different groups of participants involved in its implementation. The core objective was to better understand the opportunities and challenges of using CCDS in two 999 Ambulance Trust (AT) settings in the UK in order to improve the quality and safety of patient care for older people who have had a fall for which a 999 call has been made.

Study design

Ethical approval
The methods for the SAFER 1 evaluation were approved by the Research Ethics Committee for Wales.

Qualitative data collection

Purposive sampling
The purpose of using qualitative approaches is to maximise the research yield by drawing on the experience of those with an interest in the subject who may have something relevant to say and are willing to contribute [4].

Using semi-structured interview schedules or topic guides, (appendix 6) therefore, data were collected from three participant groups involved in the SAFER 1 trial: 1) patients 2) paramedics and 3) stakeholders, in a combination of face-to-face interviews, telephone interviews and focus groups.

1) Patients
Patients who had been i) attended by an intervention group paramedic, ii) responded to the postal questionnaire following their health outcomes, and iii) agreed to be contacted again for in depth interview, were recruited specifically. Records were linked in order to identify those patients for whom the CCDS was intended to be used, and a range of initial dispatch outcomes (taken to the Emergency Department (ED), left at home, referred to falls service). The interview schedule was intended to elicit patients’ views of paramedics using computerised software, including any associated concerns about confidentiality and data security.
2) Paramedics

All the paramedics in the intervention groups in the two AT sites were invited to participate in either a focus group or a telephone interview at two time points during: i) the pre- and ii) post trial period. Before the trial began paramedics had received a two-day classroom based training session in how to use the software. The interview schedules and topic guides were designed to examine the paramedics’ expectations of the whole SAFER 1 package (training, using the technology, and the falls referral pathways), against the actual experiences of the package, its usefulness, perceived impact on patient care, and possible directions for future development.

3) Stakeholders

The stakeholder groups were recruited purposively to participate in either a focus group or semi-structured interview following the main trial period, to include a wide range of perspectives from staff in each of the ATs participating in SAFER 1, and also local providers involved in the care of older people following a fall. The stakeholder schedules and topic guides were intended to enhance understanding of the dynamics of inter- and cross-organisational issues associated with the implementation of the SAFER 1 technology in the two 999 emergency ambulance settings.

All the discussions were recorded using digital audio equipment and transcribed.

**Analyses**

The transcripts were analysed thematically within a rectangular grid according to the principles of framework for applied policy research [5]. Multiple coding was used to validate the analytic process and to structure how the content of the transcripts would be classified [6-7]. Three researchers (PC, BW, and GT) independently familiarised themselves with a cross-section of the scripts from each dataset. A preliminary scheme for data extraction, processing and classification of the main themes and sub-themes occurring in the data was then refined and agreed in group discussion. This iterative approach between the three researchers introduced an element of objectivity into the process and guided all the qualitative analyses which were then undertaken by one researcher (PC). The coding and abstracting were undertaken manually. The data segments were grouped within a template to enable divergence and convergence of the themes to be identified and interpreted into future strategies.
Results

A total of 50 participants were recruited into the study. (Table 1)

Table 1: Participants recruited into the study

<table>
<thead>
<tr>
<th>Participant group</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>7</td>
<td>8</td>
<td>15</td>
</tr>
<tr>
<td>Paramedics</td>
<td>9</td>
<td>7</td>
<td>16</td>
</tr>
<tr>
<td>Stakeholders</td>
<td>12</td>
<td>7</td>
<td>19</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>28</strong></td>
<td><strong>22</strong></td>
<td><strong>50</strong></td>
</tr>
</tbody>
</table>

Patients

Fifteen patients (six male and nine female, with, where appropriate, the spouse or carer) were interviewed face to face. All patients had been in the intervention group, with the CCDS available for use by the attending paramedic. Ten/15 falls incidents had resulted in the patient being transported to hospital. In most cases (n=13/15) someone other than the patient had telephoned for an ambulance. Most patients (n=12) had reasonable recall both of the circumstances in which his or her fall had occurred, and also of the paramedic assessment process. For example, there were several references in the data to memories of the paramedic doing a lot of writing.

“I said ‘You’re not still writing the form’...you know, ‘the report about this [fall]’?...Took him longer to write the report [paper-based] on what had happened than it did - than it has to treat me.” [2.pt.Int.01]

“Anyway, hmmm, there always seems to be an awful lot of writing going on.” [1.pt.Int.01]

However, only four/15 recalled an attending paramedic using a computer on scene. There are several explanations for this. Quantitative findings show that usage of the CCDS was low. Some patients had poor eyesight or blurred memories of the events surrounding their fall. Finally, depending on clinical priorities, the paramedic did not always complete it in front of the patient. The patient group interviews therefore explored the participants’ views of the idea of paramedics using CCDS whether use of the technology was remembered or not. The responses ranged from supportive typified in the quote:

“because it’s a, hmmm, detailed information and he’s not relying entirely on his memory or, for that matter, his experience. No, I think it’s an excellent idea. He doesn’t have to use it, but it’s there if he wants it or if he needs it.” [1.pt.Int.01],

to negative concerns that having to refer to a computer may affect time adversely: “...time is everything” [1.pt.Int.06]

or that it could be a distraction from the paramedic priority to attend to the patient first, and damage confidence by raising questions in the patient’s mind about the levels of competence and clinical judgement expected in healthcare professionals, exemplified by the following quotes:

"I would personally worry if they [paramedics] had to look at a computer......These, chaps should, should be trained….to the nth degree, you know... they can do it afterwards if they want to or, you know, if the patient was lying on the floor, if he had to fill in a form or do
something then, well fine, okay, as long as the patient had been seen to and he knew what to do, to do his job." [1.pt.Int.06.2]

“Well to me they’re [computers] not the same as having people as human beings, it’s all sort of automatic and it might be that they don’t get the right… questions to give the right answers. I don’t know quite how to describe it. I suppose I haven’t got the same faith in them [computers] as I have in human beings.” [2.pt.Int.04]

Generally, attitudes towards e-technology were fairly sceptical:

“…Well, if the system’s working now, I don’t really see we need to change it…” [1.pt.Int.06.1]

or ambivalent:

“I never really thought about it you know”. [2.pt.Int.02]

The direction of most views however, was towards beliefs that the professional is better placed than the patient to know what tools to use:

“I mean if it helps them [paramedics] in any way to get on with whatever they’re doing, you know, their job and their work and their treatment, you know, it’s to our advantage really isn’t it?” [1.pt.Int.03]

“Well if it aids them [paramedics] fair enough, you know” [2.pt.Int.02]

Respondents were asked specifically about any concerns about data confidentiality related to use of the computerised system. The question yielded a range of views about the security of patient information but no specific concerns about data being held on computers. There was an implicit presumption that access to, and the confidentiality of, all health information is protected.

**Paramedics**

In total, 16 paramedics (12 male and four female) in the intervention groups in the two sites took part in the pre and post trial interviews and the focus groups. Ten/16 participants contributed to both periods of data collection. The data confirmed that the samples achieved were sub-groups of paramedics in the intervention groups who were committed to doing a better job for their respective ATs and for older people who may fall frequently:

“…a lot of the staff that did enlist into the SAFER trial, had an interest in falls and falls prevention anyway. You didn’t tend to find people who weren’t …” [2.post.Int.07]

The post-qualification experience as a paramedic in the two groups ranged from three to 20 years. Participants worked as lone responders in cars known as rapid response vehicles (RRVs) or as part of double-staffed crews on Emergency Ambulances (EAs).

**Pre-trial expectations**

The pre-trial data indicates that the motivations of paramedics to be involved in SAFER 1 can be characterised as personal (an interest in computers and/or research and improving job satisfaction), educational (a self-directed approach to learning new skills), professional (to assist with their continuing professional development (CPD) as part of their registration), operational (through standardising paramedic practice and doing a better job), and organisational (to help the AT provide a better service for elderly people who have fallen who constitute a large proportion of emergency 999 calls) [8].

Participants revealed a combination of positive and negative expectations of the usefulness of the SAFER 1 technology to paramedic practice.

“…the bottom line is I like this [idea of CCDS] because I have got evidence to show that I have thought about what I am doing…” [1.pre.FG2.page24]
“...I think there’s a lot of repetition [between EPR and CCDS]...I think that’s gonna be a problem....I mean just in terms of time....I mean, at the end of the day, you need a bit of kit to work, don’t you?” [2.pre.Int.01]

In Site 2 some of the views expressed may have been influenced by previous experience of using the EPR when reportedly enthusiasm had wavered over time and paramedics had reverted to a paper-based system.

“...we recognised that turnaround would be slower and kind of put up with that, but this was really before Call Connect, which is when they changed how they record the ambulance times, came in. But, since then, there’s been absolutely no pressure to use the – the electronic stuff....And we haven’t been pressured not to use paper.” [2.pre.Int.03]

It was clear that in practice, the paramedic participants expected the real value of the CCDS to be in supporting their clinical decisions in borderline cases when a patient did not appear to have been injured in the fall and ostensibly therefore may be able to be left at home safely rather than conveyed to hospital.

“...It’s the ones [falls patients] that are, “Well, do we need to take them to hospital or not?” That’s where this package would be invaluable, because you can go through the questions and it would sort of back-up your thoughts, if you like.” [2.pre.Int.02]

“...I have been to situations where you think: Well, you know, it’s – am I playing Russian roulette here, or am I making a good clinical decision?” [1.preFG1.pp28]

There was no indication that participants expected the CCDS to substitute for the actual clinical decision which would stay with the paramedic.

“...I can’t see it [CCDS] being any risk, because ultimately the decision is gonna be ours.” [1.preFG1.pp39]

Considering the wider implementation of the technology, it was recognised that deciding to transport or leave someone who had fallen at home was a shift away from protocol-driven practice towards clinical decision-making, and that the increased responsibility may not be welcomed by all paramedics:

“If you are confident to be autonomous and you are happy with your level of knowledge and skills and you are happy to make decisions, but if the training is not backing it, and if you are not happy within yourself, you are not happy.” [1.preFG.2.pp8]

One view was that the SAFER 1 paramedics may be seen as ‘agents of change’ in that seeing the technology in use may encourage colleagues to become more confident at making decisions autonomously:

“...They are all going to say oh great. They would be more confident hopefully at making decisions and leaving people and making referrals, etc.” [1.preFG.2.pp24]

Other views however anticipated challenges in getting paramedics who may be resistant to what most participants regarded as potentially beneficial for the AT and patient care, to adopt the technology routinely into clinical practice unless there was clear strategic direction from the senior management team:

“...once you make it compulsory, there’s no ifs or buts, you’ve gotta do it.... part and parcel of your policies and procedures...once it becomes policy there’s no way out...” [1.preFG.1.pp47]

Variation in how comfortable some staff felt about using computers was also identified as a possible challenge to implementing the technology:

“...I’m sort of a two-touch typing, and a – like that, you know, so it’s gonna take a little while to get used to it ... I don’t know how that’s gonna fit in with the whole – over the whole of the ambulance service when they want you to turn around as quick as they can.” [1.preFG1.pp1]
Post trial experience

Training

Satisfaction with the training varied and appeared to be linked to previous exposure and self-rated competence and confidence in using computers:

“...I did get a little bit lost in it, but, when I had the tablet and I had a bit of more – a bit more time, and I had the paperwork as well, I managed to get into it okay then, no problem at all....Hmmm – if I’m perfectly frank, I think they – there seemed to be one gentleman promoting the system, rather than the SAFER pathway, and that wasn’t something that I needed to get into, because, you know, as I said, you know, I’m – I’m not – I’m not very good with IT skills anyway...” [1.post.Int.04]

“...Hmmm, I’m quite computer literate so, from that perspective, I felt it was more like, you know, once you’ve had your initial training it was going away and using it for real and practising, you know, with, hmmm, made up patients....” [2.post.Int.01]

Use

The frequency with which the CCDS was used during the trial period differed between the two intervention sites with participants in Site 2 reporting more consistent use than Site 1. Use may have been influenced by previous experience and operational differences between the two sites. Before the trial, Site 2 had experience of using an EPR and the systems and processes needed to support operational use were in place. These systems had to be developed in Site 1 and this led to delays between paramedics receiving the training and using the technology in practice. Loss of momentum was raised by Site 1 participants as a factor that may have dampened initial enthusiasm for using the technology:

“I feel a bit disappointed that I was quite keen when it first started and it just never seemed to gather that momentum that I thought it would gather.” [1.post.Int.02]

The data from Site 1 indicated that if an RRV is dispatched to a fall, an EA is also dispatched, reducing the time available for a lone responder in the RRV (who may also be a SAFER 1 intervention paramedic), to use the CCDS for the assessment before the crewed ambulance arrived.

“I found that, on the RRV, if you had an elderly faller that had injuries, you had a very, very narrow window to work in, because you knew there was an ambulance coming to back you up.” [1.post.Int.04]

Conversely, in Site 2 the data suggests that RRVs were prioritised to Category A and B calls, and were not dispatched routinely to falls that may be prioritised as Category C calls. The potential implications of variations in dispatch for the frequency that the technology was used is that more intervention paramedics in Site 1 than Site 2 may have been by RRVs, resulting in the workload in Site 1 resting on lone responders. More intervention paramedics in Site 2 than in Site 1 may have had opportunity to share the workload with a colleague:

“...generally to ease things and to speed things up I’d have a colleague doing the paper report form whilst I did the SAFER [CCDS] software.” [2.post.Int.01]

Perceived impact on operational processes:

All participants felt that using the technology was associated with longer times on scene or, if the software was not completed before arriving at hospital, prolonged hospital times

“... I wouldn’t necessarily always complete the software [CCDS] in front of the patient” [2.post.Int.01]

This was seen to conflict directly with the organisational priority to meet national standards which are time specific:
“...if the patient is very ill and needs you with them and so you can be delayed a little bit after the job then, ...but basically the employer--, you know, bosses or whatever, we have to do things very quickly and turn around quickly.” [1.post.Int.05]

“...Time seems to be a big, big problem. That, hmmm, it was additional time on the scene or, you know, you didn’t necessarily have the time if you were dealing with a poorly patient or person that needed your care, or you only had a short journey to hospital, so then your hospital times could become prolonged...” [2.post.Int.01]

Despite an alternative view in the paramedic data to the effect that the longer time on scene completing the software provided an opportunity to observe the patient and improve the quality of the assessment:

"...it gave me time with the patient so I could keep an eye on them and see what they actually were like..." [2.post.Int.04]

The data revealed that pressures on time, whether perceived or actual, may have contributed to the frequency with which paramedics used the technology.

Utility of CCDS to paramedics

Variations between participants across both sites were apparent in the perceived utility of the CCDS for their practice. A recurring view was that CCDS may be more appropriate for rarer conditions than falls (which paramedics tend to gain a lot of experience in assessing), or for less experienced practitioners for example, student or newly-qualified paramedics, technicians, lay responders:

“... Hmmm, I think it perhaps has a greater place with, perhaps, hmmm, student--, no, student clinicians, newly qualified clinicians... ” [2.post.Int.01]

or in face-to-face consultations in primary care settings:

“...I can see a place for the CDS in a more primary care centre.” [1.post.Int.01]

The CCDS was also seen to have a potential role in assisting decisions for patient groups other than older people:

“...I think there’s parts of it [CCDS] you could use for all patients in truth...” [2.post.Int.04]

The post-trial interviews tended to confirm the expectations in the pre-trial data that the CCDS would not change the paramedic’s clinical decision either to leave the patient at home after his or her fall, or convey to hospital:

“...I was using it [CCDS] as a trial but I always felt that I was going to be the one who made the decision ...regardless of what the software came up with...” [2.post.Int.03]

“...I used the hmmm, the SAFER software because I was involved in a trial but it didn’t sway me against my decision whether or not to leave somebody at home or not..” [2.post.Int.01]

This was because although the CCDS was associated with “spreading the risk”[2.pre.Int.02] ultimately, the responsibility for the decision made and for anything adverse that may happen to the patient in the subsequent period was seen to stay with the paramedic.

“...it’s kind of my reputation, my registration etc., on the line.” [2.post.Int.03]

There were however a lot of indications in the data that the software did influence the process by which the paramedics came to their decisions suggesting that the CCDS may be an ‘instrument of changing practice’. The effect of the software in encouraging decision-points to be more transparent and raising confidence was manifest in the data in several ways.

For example, by raising awareness:

“It – it didn’t – it didn’t make – no, it won’t make any difference with the decision-making, but what it did do is – it’s like the one that had the – the example I – I made – that I gave you earlier, .... it opened my eyes up to: ‘Well, why this – why is this person falling?’ You know,
more of a reason and more of a background to the fall, rather than just a straightforward fall.” [1.post.Int.04]

Prompting paramedics to reconsider how they had made their initial decision:

“I think even if that [CCDS] was saying, ‘Take them to hospital’, I would have looked twice and gone; ‘Why?’ I would have gone into the help boxes to find.....to understand why those answers were important....So no, I wouldn’t have said it influenced...” [1.post.Int.01]

or an improvement to the manual aids that some paramedics may rely on usually:

“...that’s why I always carry my own Clinical Guidelines in my pocket, with me, ‘cause it’s a pocket guide we have – the paramedics...’Cause I’m not perfect... And I always think it’s good to look back at things and self-review really...And then that machine’s [CCDS] doing it for me while you’re actually filling out – filling it out, isn’t it?” [2.pre.Int.04]

Whilst the CCDS was not acknowledged as impacting on the paramedic’s decision, most participants acknowledged that having the software as a back-up was reassuring and increased his or her confidence:

“... it was nice to have that [CCDS] supporting your decision...nice but it wouldn’t.... it wasn’t making my decision for me.” [1.post.Int.01]

As predicted in the pre-trial data, the software was felt to be useful for falls assessments of a sub-group of older patients who had fallen i.e. those whose condition was not time critical:

“...you wouldn’t fill the software out was if you had a time critical patient you took to hospital. It was anticipated that you would do-- , use the software if you took somebody to hospital, hmmm, but obviously if they were stable...” [1.post.Int.03]

“...There were some jobs where the patient was off the floor, for example, and you knew full well that they were mobile when you got there, you’d use it straightaway. Other times you would deal with that patient straightaway and you may not start using the tablet until ten minutes, quarter of an hour into the incident.” [1.post.Int.01]

There was one report of an intention to use it [CCDS] again if it was available: “...Oh yes, I – if I still had it I’d still use it...” [2.post.Int.04]

More generally, the view was that the content and usability of CCDS needed to be refined before its use would become accepted widely by paramedics:

“I think there would have to be developments before I became a sort of regular user.” [2.post.Int.01]

Despite some variation in views between sites, and between participants within and across both sites, a core set of benefits (Box 1) and barriers (Box 2) relating to the use and perceived value of the technology emerged fairly consistently.
Box 1: Benefits of technology

**Administrative**

- **Standardised approach:** “...you know you can have quite a methodological approach to it so you just sort of flick through, you know, the different screens...” [2.post.Int.01]

- **Simple and straightforward to complete:** “…It [CCDS] was quite a very simple basic straightforward...hmmm, which is good...” [2.post.Int.01]
  
  “…The ePRF I found very, very simple. I found that-- that good.” [1.post.Int.03]

- **Improved storage and retrieval of data:** “…electronic way is a better way of storing data. And so from an auditing purpose and a collating purpose it’s you know, it’s ideal...” [2.post.Int.02]

- **Improved quality of information:** “…you can put more data on it so if you’ve got a patient that you need to write quite a detailed history on, it is quite a good tool...” [2.post.Int.02];
  
  “So you can put more detailed information...regarding medical trauma, whatever...” [1.post.Int.05]

- **Improved legibility:** “…Well, it’s [electronic record] clearer isn’t it.... it’s a struggle sometimes to just – to understand what’s been written.” [2.post.Int.04];
  
  “.well, obviously your handwriting is one [laughs] which is--, it seems a bit pathetic but on the back of an ambulance, you know, you’ve got to quickly try and get your information down on paper which can be a bit of a nightmare.” [1.post.Int.05]

- **Improved security:** “…At the end of your shift you stick your forms [paper] in a tray in the corridor...so any Tom, Dick or Harry can just pick it up and look at it...or it’ll get lost in the system...whereas an electronic one...once you’ve finished it, that’s done isn’t it” [2.post.Int.04]

**Value to paramedic**

- **Documented decision-making process:** “I liked it [CCDS] because it gave you some form of documentation that you had done a formal falls assessment...because at the moment we’ve got no real formal assessment.” [2.post.Int.04]

  “…if you were not going to take somebody to hospital and that decision was patient-centred, if anything adverse were to happen after it I think if you’d...it that CDS would have given the same answer at least that’s some kind of evidential practice that this decision was right.” [1.post.Int.01]

- **Reminder of the need to take certain actions:** “…It [CCDS] did highlight – a couple of times it did highlight things I hadn’t thought about...just remind you to do sort of...do the things you should do...” [2.post.Int.04]

- **Useful to have access to information:** “…tweaked your skills a bit...” [2.post.Int.04];

  For example: JRCALC guidelines, and the British Formulary (medicines guide), especially for rarer syndromes; “…If there’s an area that you’re a little bit grey on, then you can look into that and just get a little bit of a refresher...”; [2.post.Int.02]

- **Continuing professional development:** “…it raises your awareness for your own professional development... because you’re continually learning about new things and involved in that software and evidence based rationale, or hopefully evidence based rationale, why it’s working or why it’s being asked.” [1.post.Int.01]

- **Changing ways of working:** “…I think it changed my mindset with what-- yeah, what type of people or what injury patterns and what other pathways are available for us to access” [1.post.Int.01]
Benefits for patients

- Distance “...we’re a long way from the hospital and so there’s the kind of decision to leave people at home or take people to hospital is – is quite an important one, in that if we’ve got an old lady who doesn’t need to go to hospital, so it’s actually would be better for her, rather than dragged out 20 miles away.” [2.pre.Int.03]

- Safety “...That again, needs to be done in a safe manner – meant that she’s in sort of – in a safe and practical manner.” [2.pre.Int.03]

- Appropriateness “...The benefit is that we-- at the moment as I say we take everything to hospital, if you go to create a different pathway for them [older patients], you know, the benefits are that they don’t sit having [to wait] hours on end... they don’t have to go to hospital, they get... they get a more appropriate care pathway.” [1.post.Int.02]

Potential impact on wider system

- Reduce unnecessary 999 journeys, ED attendances and hospital admissions.
  “...at the moment it seems like we-- we take everything to hospital and I’m always looking at if there are other services out there that we can integrate with and it’s more beneficial for the patients not to attend an A&E but go to an alternative care pathway..” [1.post.Int.02]

- Possibilities of integrated electronic communication systems: “…if it was, hmmm, developed so it was-- it was faster or, like I said, rather than having two systems if it was at the end of the PRF and you could send-- so it could be used on any job, so if it was a diabetic you could just press a button, like, click to diabetic referral, click to epileptic or GP and, in that way, it can just go through.” [1.post.Int.03]

Box 2: Barriers to using the technology

Practical/logistical constraints:

- The hardware was described as “cumbersome” or as “an extra bit of kit” [1.post.Int.01] for the paramedic to carry into the house. For lone responders in RRVs this may mean more than one trip between the vehicle and the house;

- In moving ambulances, the equipment was capable of falling off its cradle: “I think that the holding brackets needed to be tightened. They were just, er--, they were just... the actual holding bracket...is quite wobbly.” [1.post.Int.03]

- Location of equipment:
  “if you can imagine the logistics of trying to print it out in an RRV. If it’s pouring down with rain you’ve probably got it resting on the back – the back seat...in the – in the inclement weather, so from your waist down you’re soaking -- [laughs] you’re soaking. [1.post.Int.04]

- Thermal printing paper degrades over time: “…our vehicles use [thermal roll] printer paper so the quality is not 100% and they...fade with time...” [2.post.Int.01]

Network and hardware constraints

- Reliability of the wireless network: “...Most of the time that [internet connection] was OK. I mean there’s a couple of places...because we’re a rural area...there’s certain places where you – you can’t even get a mobile phone signal.” [2.post.Int.04]

- Speed of the system: “…slow for information to upload because of the telemetry issue. ...It [CCDS] was inherently easy to use. It was nice to see the help boxes on it to explain why this certain question was asked. ... Hmm... but it was slow.” [1.post.Int.01]

- Battery charging in vehicles: “…the battery life is not the length of a shift...it’s shorter...so ...the equipment needed continual charging...” [2.post.Int.01]
Software

- Mismatch between CCDS assessment and paramedic clinical practice: “...a better layout for the software, to have made it in a more chronological order of things happening. Not chronological, but in a better order. Hmmm, more user friendly.” [1.post.Int.01]

- Repetitive data entry: “...quite often as you would go through the different screens...like exams, questions would be repeated and you’d have to re-enter information.” [2.post.Int.01]

Time factors

- Having two systems running in parallel – electronic and paper increased workload: “...I was trying to do the paper – the electronic ones first but obviously, I have to leave a paper copy with the patient...” [2.post.Int.04]

- Clinical priorities “...on the rare occasion when we’ve had three people in an ambulance one person actually did fill in the actual software [EPR], ... you do need almost need someone who’s sole job-- , sole job is just to use that, that piece of software...” [2.post.Int.03]

...Pressures on time increase if you are on your own....

- “...Because also you don’t have a crew mate to do both and also, I mean, it kind of depended on how some people-- , you know, some crew mates would be prepared to kind of get involved...” [2.post.Int.01]

- Reliability of operational support: “...there was never, ever printer paper ...I was up against a brick wall every single day, every time I tried to use it initially ... And then I couldn’t get online ... problems with my password...” [1.post.Int.05]

Perceived impact for patients

- Potential to distract from the quality of the patient assessment: “…you tend to, if you’re not careful, concentrate on filling out the boxes at the expenses of not actually speaking to the patient or the patient's relatives, or both ...which could be a bit of a problem... I personally went out of my way not to make it a distraction.” [2.post.Int.02]

“...the tablet itself didn’t sit upright. So typically I tend to work on my knees on the floor...So then you found that you were head down. That's all the patient saw was the top of your head, because you were bending down looking at the floor...” [1.post.Int.01]

...Outstaying your welcome:

- Longer times on scene are not welcomed by some patients or carers: “I mean...I mean a couple of relatives have said: ‘well this is a bit long-winded’. [2.post.Int.04]

- “…a lot of the people we’re going out to are ... quite ...cantankerous and all they want is to be lifted off the floor ... And then they want you to, hmmm-- , to b***** off.” [1.post.Int.03]

Perceived impact on wider system

- “...in reality the paper one [EPR] is...it seems to be preferred by most ambulance staff and most hospitals.” [2.post.Int.03]

“...if you start talking about doctors from hospitals then they wouldn’t know about the project [SAFER 1]. So it was kind of like we were in our own little... our own little bubble really...” [2.post.Int.01]

**Paramedics views about possibilities for future development**

The paramedic data indicated that the technology was associated with definite benefits for patients, paramedics and the service. Focussing on the issues within the influence of the paramedics, the ability to complete the software in a timely way, and to maintain continuity of operational support to facilitate its use, emerged as important challenges to be overcome. Although it is not possible to separate out differences in the length of time that intervention paramedics spent completing the EPR, and the CCDS, participants expressed the view that the process would speed up with use and practice. The recurring frustrations at having to enter the same data separately into the CCDS and the EPR, (which has implications for software development and time), implies that where more than one package is being used, the
software needs to be integrated so that shared fields are populated automatically when the information is entered once. In respect of the software development, the analysis pointed to a need for closer involvement between software designers and a cross-section of paramedics to create a more ‘user-friendly’ product [9] with flexibility to override some fields, and improve the layout of the content. Increasing the space available in the CCDS to record multiple medications, which may influence a paramedic’s decision to convey or refer, was raised specifically. Further, the need to adjust the order of clinical assessment in the CCDS to more closely resemble paramedic priorities and clinical practice was identified. One paramedic suggested that a ‘red flag’ system to highlight certain symptoms or diseases within a community that needed special consideration may be a useful addition to the CCDS.

In respect of operational support for the technology, in site 2, having a proactive contact in the AT – ‘a product champion’ who assumed the role of liaising between the paramedics and the various technical and operational support teams to resolve problems quickly was seen as an important facilitator to the implementation of the intervention.

“If I had any problem I used to go through [NAME] anyway, because ...it was actually sometimes easier because [NAME] already built up a big rapport with the IT people who were looking after the SAFER software. So if I had a technical issue I’d go through [NAME] ... so I didn’t actually at any point really need to contact IT directly.” [2.post.Int.07]

“Don’t ask me who it [IT support] was, because I actually can’t remember but....Any trouble that we had with it [technology], I actually talked through with [NAME] seeing [NAME] is on my station anyway. [2.post.Int.06]

“I think [NAME] was actually quite supportive and – if [NAME] couldn’t answer something [NAME would] always find out for you, and point you in the right direction. I’d give [NAME] 10/10 for that. ” [2.post.Int.07]

The capacity also in Site 2 to transmit records electronically for printing out at the AT, seemed to alleviate some of the earlier challenges associated with printers on the vehicles and poor quality thermal paper:

“So we sort of got – we got that sorted out in the end with our IT department so we could email them ...instead ...yeah, more user-friendly.” [2.post.Int.04]

Stakeholders

Nineteen participants took part in the consultation with stakeholders. Most participants had different roles in the two ATs although views from an emergency department (ED) consultant in each area and input from members of a falls service involved with the trial were also incorporated. (Table 1) The ED and the falls service participants did not perceive that the SAFER 1 trial had any impact on their services.

The benefits and barriers to using CCDS and the EPR evident in the paramedic data (Box 1 and Box 2) were also present in the stakeholder data. The technology was seen to be associated with substantial benefits for the two ATs, for patients and other providers. Site 2 had come into the trial with a legacy of poor experience of using EPR. At Site 1 the implications of linking into a central secure IT network that was outside the control of the AT and the layers of governance and complexity that this added in getting the trial underway had not been appreciated by the AT at the outset. For both sites however, participation in SAFER 1 emerged as having been a useful developmental experience that highlighted issues and possibilities which could be expanded and improved upon in the future.

The main operational issue evident across both sites was tension between having to provide an emergency ambulance service in line with current standards:

“...running services as per normal...” [2.sh.Int.04]
and introducing new equipment and clinical working practices to benefit patients and service providers in the future that need training and development time to be incorporated into operations routinely.

In respect of the patterns of use of the SAFER 1 technology during the trial, a more user-friendly product:

“...usability is one of the critical areas that everybody forgets...”, [2.sh.Int.04]

Improved communication, and the need for clear systems and processes that will withstand personnel, shift and organisational changes, emerged as important mechanisms to provide the continuity of support necessary for the software to be utilised.

The patterns of paramedic use and non-use of the technology anticipated by one stakeholder interviewee in Site 1 was attributed to the motivation and perseverance present in individuals. Use was predicted by paramedics who were used to:

“...working with problems and trying to resolve them...” [1.sh.Int.03]

Non-use was predicted in paramedics who had “...hit a wall and decided it was too much of a wall to get over...”[1.sh.Int.03]

This interviewee was linking predicted use and non-use of the CCDS to differences at the individual level in how paramedics resolve problems rather than to connectivity issues or the reliability of organisational support This view diverges with detailed reports by paramedics of thwarted attempts to use the software operationally, lack of continuity of support to resolve problems associated with use, and the motivations of the paramedics who participated in the Trial. The stakeholder dataset also suggests that attempted use of the CCDS by paramedics in site 1 was considerably higher than the use actually achieved. Although a blank record was saved whenever a paramedic logged into the system, if for some reason, for example:

“....they’d start doing the CDS and they’d lose signal...” and “.... it just crashed and they had to start all over again...” [1.sh.Int.01]

that record was deleted routinely.

“...in the morning there might be three blank records there...” [1.sh.Int.01]

**Stakeholders views about possibilities for future development**

The additional opportunities for the future development and use of the technology identified in the stakeholder dataset were voice capture software, I-pad type models which were felt to be more cost effective for the ambulance service, and an end-to-end process linking IT systems within the ATs, and also between the ATs and other providers.

**Discussion**

**Main findings**

This qualitative study was undertaken to improve understanding of the processes and perceived impact of using CCDS for elderly people who are attended by paramedics after a fall in two different pre-hospital settings in the UK. The study was designed to complement the clinical effectiveness and costs studies in the SAFER 1 trial by addressing specific issues around acceptability and usability of CCDS and its perceived impact for the quality of patient care, paramedics, and the organisations involved.

Analyses of data from all three participant groups (patients, paramedics and stakeholders) converged around the importance for the technology not to distract paramedics from the quality of the interaction with patients and carers. The prevailing view in the paramedic and the stakeholder data was that computerised data is more secure than paper records. Patients did not raise any specific objections or security issues around the idea of their personal data being recorded on a computer.
Despite organisational and operational differences between the two AT sites, the paramedic and stakeholder datasets across both sites revealed consistency in perceptions of the benefits and barriers of CCDS, and of the strategies for future development. It was felt that the software would be useful for training purposes and for newly qualified practitioners. It was also seen to have a role for assessing conditions other than falls. Although the CCDS was not expected nor seen in practice to substitute for the paramedic’s clinical decision to take the patient to hospital or not, the software was attributed to having positive influences on their decision-making processes, for example, by raising awareness of underlying morbidity, prompting actions that had been overlooked, or a review of how the decision had been made. Paramedics also appreciated the educational advantages, and the formal back-up for their decisions, that the software provided. The main barriers to using CCDS revolved around the reliability of the wireless signal especially in more rural areas, the hardware, and the configuration of computer systems, rather than the potential and acknowledged value of CCDS in reassuring paramedics, patients and their families about the safety and appropriateness of the referral pathway.

In respect of future development of the software, the dominant view in the paramedic and stakeholder data was that the content and overcoming some of the logistical challenges of using CCDS in an emergency ambulance setting identified in the study would benefit from collaboration between a group of paramedics (as end-users) and the developers.

The main process and operational impacts to emerge were increased workload and longer times on scene which were seen to conflict with organisational priorities for a rapid turnaround in order to meet existing national standards. These time pressures seemed to be exacerbated or relieved depending on whether the paramedic was a lone responder in an RRV, or a member of an EA (which afforded the possibility for more timely completion of the clinical assessment and the patient record by sharing the tasks with a colleague).

**Comparability with existing literature**

Qualitative studies of the benefits and barriers to the use of CCDS in nurses [10] and GPs [11, 12], and doctors [13] have been reported previously. As far as we are aware our study is the first to examine the views on the use and acceptability of CCDS in a pre-hospital emergency ambulance setting in the UK in three key groups (patients, paramedics and stakeholders). Our findings resonate closely with those of existing studies conducted with other health professionals and settings [10-13]. One study identified that the organisational triggers to increase the use of CCDS by nurses are clinician engagement, adequate training, a supportive environment, and system characteristics [10]. Our findings that the CCDS increased pressures on time, the appreciation of the educational advantages, that the software may be useful for training purposes [12], the potential limitations of IT skills, and the need for developers to better understand the needs of the end users, have all been reported previously [10-13]. Our study identified additional challenges around the implementation of computerised technology in a pre-hospital EA setting. The logistical issues relating to portability, recharging batteries, the reliability of the internet connection in mobile units, the location of printers, the availability and quality of paper supplies, were not found in the UK studies of nurses [10] and GPs [11]. Some of our additional findings however, were also reported in a study of US doctors [13] which implies that the opportunities and challenges of using CCDS are setting dependent.
**Strengths and limitations**

The qualitative study was undertaken to complement and supplement the quantitative findings. Participants were recruited because of their likelihood of being in a position to contribute to the process meaningfully. Securing the co-operation of a sub-group of paramedics in the intervention group with an interest in falls and falls prevention and who were fairly homogeneous in terms of enthusiasm and motivation at the outset for SAFER 1, stakeholders in key roles within the organisations involved, and older patients who expressed a diverse range of views about the use of computerised technology in emergency care, are significant strengths of this study. The use of a combination of focus groups, telephone, and face to face interviews to collect the data, rather than a single approach to data collection may not be ideal. However, SAFER 1 was a pragmatic trial conducted in emergency ambulance settings and gathering the qualitative data had to be flexible according to the availability and preferences of the participants. Each method was conducted systematically using semi-structured schedules. All the textual data yielded wereanalysed thematically by the same researcher using Framework techniques [5]. The multiple coding of extracts of data from all three datasets preparatory to the analyses is a recognised way of validating descriptive and interpretative data [6,7]. A more detailed analysis may have resulted from using software, for example NVivo (http://qrinternational.com/) or MAXQDA (http://www.maxqda.com/) to assist with the coding and charting of the data. However, analytic packages for qualitative data may not reduce the time for data handling [14]. The SAFER 1 qualitative data sets, though substantial, were not unmanageable, and the additional time to use software to assist the process was not available. The texts were coded manually. Segments were abstracted into a template enabling divergence and convergence of themes within and across the three datasets to be identified. As expected, because of how and why the information was sought, diversity in the themes was fairly narrow, so to anchor diversity we adopted the principle of ‘polarity’ and interpreted the findings into strategies for future directions. Within the context of the two AT sites, the consistency in the perceptions of the benefits and barriers evident across all the data, together with the comparability of our findings with those of previously published studies in this field, encourages us to be confident in the robustness of the findings.

**Conclusion**

Despite the need to resolve several organisational and operational challenges (mostly related to logistics and hardware) associated with implementing CCDS in the two EA settings in the SAFER 1 trial, the software is associated with positive influences for supporting the personal and professional development of paramedics, and benefits to organisations of improved information management of having a cadre of clinical staff prepared to question their own practice in order to do a better job for patients. The analysis also yielded positive directions for paramedic training, identified necessary support mechanisms that need to be in place to enable new technology to be implemented in an emergency re-hospital setting, and directions that may shape the future development of the software. These findings offer significant advantages for patients, paramedics, the ambulance service, and wider systems of emergency and urgent care.
References


Chapter 7 Discussion

In this report we have presented the results of work we have carried out to set up and undertake a cluster randomised controlled trial of computerised clinical decision support (CCDS) software for paramedics to use in the assessment and planning of care of older people who have had a fall and for whom a 999 call has been made.

As contracted and agreed with our funders, we have presented, as individual stand-alone chapters in the form of papers to be submitted to scientific journals: the background; aims and objectives; methods; clinical and cost effectiveness results and qualitative findings concerning the views of stakeholders including patients, participating paramedics and NHS managers.

In addition, we have included a chapter (again, in the form of a stand-alone paper) which presents the challenges we encountered, and largely overcame, in setting up this trial of an IT intervention in the dynamic real life setting of emergency pre-hospital care. A full systematic review is underway, through additional PhD funding gained to enhance the SAFER 1 trial, included as an appendix, as a draft. These are additional outputs, which, although not part of our original contracted work, have produced valuable learning from this study and which we plan to publish in their own right, in the scientific press.

Key findings from across the trial

Systematic review (separately funded, work in progress, preliminary results):

Few RCTs of CCDS have been carried out in the emergency care setting, and no primary research studies of any design were identified from within prehospital emergency care.

Empirical studies in the emergency setting were all based in ED or Walk in Centres. Findings related mostly to rates of usage and effects on processes of care, with very little information about effects on patient outcomes. Implementation and adoption issues were described qualitatively in some studies, highlighting the need for improved usability and support underpinning implementation.

Overall, the results of the systematic review reinforced the need for the SAFER 1 trial to provide evidence about the clinical and cost effectiveness of CDSS in prehospital emergency care, and about factors which affected implementation within services and adoption by ambulance paramedics.

After the fall: Trial implementation

A descriptive analysis of the set up and implementation of the RCT highlighted the challenges of carrying out experimental research in prehospital emergency care, and ways in which we largely overcame these challenges in SAFER 1. In this chapter we have drawn out learning which is generalisable. Challenges encountered related to the development and implementation of both the health technology itself and the RCT methods.

In particular, various external policy events and demands caused delays in implementation of the trial, related to:

- Ambulance service mergers
- Stop start nature of a national programme of electronic patient report form (ePRF) implementation which affected the context for the development of the CCDS software
- Increasing pressure on ambulance services to respond to higher volumes of emergency calls within tight performance targets (and introduction of ‘Call Connect’)
- Increased requirements for research and information governance during the study period
Whilst these challenges were largely overcome as the trial was brought to a successful conclusion, they did lead to delays, increased costs and some differences and limitations in the configuration of the intervention at each site. Factors which helped resolve problems included project management strategies, engaging ambulance service paramedics in protocol development and data capture and funding designated ambulance service personnel to link study services and the research team.

We have shown that it is possible to conduct an RCT of a complex intervention in the emergency pre-hospital setting but in future the processes involved can be improved by continued development of research capacity within ambulance services and aligning research activity with strategic priorities and service objectives.

**Clinical Effectiveness:**

42 paramedics and 779 patients were recruited to the trial across two participating ambulance services.

CDSS was reported to have been used in 12% of included cases – 2% at site 1 and 24% at site 2.

The proportion of patients referred to falls services was twice as high in the intervention group as in the control group although the higher non-conveyance rate did not reach statistical significance and differed between sites. Job cycle time was lengthened by 9 minutes. No differences were found in clinical documentation levels which were high (>90%) in both arms of the trial.

Reported CCDS usage varied widely but was highly associated with non-conveyance, referral to falls services and increased job cycle times, again with some differences between sites.

**Cost effectiveness:**

We estimated the cost of implementing the CCDS intervention as £154 per patient recruited. We also estimated the mean cost of emergency health care as £2981 in the intervention group and £2567 in the control group – a non-significant difference, which includes a significant difference in the cost of referrals to falls services (p = 0.014).

Over 30 days, the costs of the SAFER 1 intervention were not offset by reductions in emergency health care use or improved health-related quality of life. However limiting follow-up to 30 days omits the medium- and long-term effects of the intervention, notably referrals to falls services. So our analysis could not detect any of the benefits of this pathway.

Logan’s concurrent randomised trial to evaluate referrals to falls services found major improvements in the numbers of falls and fall-related ambulance trips per person over 12 months, and scores on the Nottingham Index of Activities of Daily Living and the Falls Efficacy Scale. Hence the statistically significant doubling of referrals to falls services, and the intervention cost of only £154 per patient, suggest that CCDS has the potential to yield value for money. Hence more research is needed to evaluate CCDS definitively, notably with a longer follow-up period to study changes in quality of life and the costs of falls services.

**Qualitative findings:**

Qualitative findings shed light on the quantitative findings, helping to explain low usage and to provide information about how the intervention was both viewed and experienced by the various stakeholders.

Patients, paramedics and other ambulance service and NHS partner stakeholders were all positive about the potential benefits of CCDS in the emergency prehospital setting.

Paramedics reported varied experiences of use, largely depending on local factors including system configuration, although they did report that the CCDS positively influenced how they made decisions. Some advantages relating to electronic data capture, access to clinical guidelines, new pathways of care, and the potential to improve patient care and data transfer,
were also cited. However, limitations in the usability of the software in its current form were frustrating, and organisational support for implementation was lacking. The main challenges to use related to hardware and non-integrated software, operational impact (time on scene), and reliability of organisational support.

Patients and paramedics expressed some concern that focussing on the IT intervention could take the paramedic’s attention away from the patient.

Stakeholders, including ambulance service operational, clinical and IT managers, discussed possible strategies to meet the challenges of implementation in an operational setting in which the meeting of performance targets was paramount. These included improved communication, refinement of the CCDS software to be more user-friendly, resolution of logistical, connectivity and hardware issues, and the development of robust systems to maintain continuity of support

Overall, qualitative findings indicate that despite the need to resolve several organisational and operational challenges (mostly related to logistics and hardware) associated with implementing CCDS in the two EA settings in the SAFER 1 trial, the software was associated with positive influences for supporting the personal and professional development of paramedics, and benefits to organisations of improved information management. The analysis also yielded positive directions for paramedic training, identified necessary support mechanisms that need to be in place to enable new technology to be implemented in an emergency re-hospital setting, and directions that may shape the future development of the software. These findings show that CCDS can offer significant advantages for patients, paramedics, the ambulance service, and wider systems of emergency and urgent care.

Limitations

Challenges related to changes in policy, ethics, research and information governance requirements and processes and the emergency prehospital operational context led to some changes to the study design. The trial only included a short term outcomes (at 1 month) which, although it provided a useful indicator of the safety of the new health technology (risks would be mainly associated with non-conveyance and would result in further emergency episodes or death in the short term), would be unlikely to detect longer term health benefits associated with the effects of care provided by the falls service. The intervention was not fully integrated with the electronic data capture systems in place for the trial and there were usability problems that resulted in lengthened on-scene times and low usage, reducing the power of the trial to detect effects on health outcomes.

Qualitative data were collected from a range of stakeholders but through a mix of methods – individual face to face semi-structured interviews; telephone semi-structured interviews and focus groups – which is not ideal in one dataset. However, the number of participants across services and stakeholders strengthens the findings reported.

Conclusions: implications for policy, practice and further research

The SAFER 1 trial has delivered encouraging results related to the implementation and effects of CCDS in prehospital emergency care, especially on processes of care of older people who have a fall and call 999. The trial was undertaken in two ambulance services in England and Wales and was close to meeting its revised sample size.

Although no effects were found on health outcomes, our principal process outcome of pathway of care following the emergency attendance showed that referrals to falls services were doubled in the intervention group. Linking these findings on referrals with recent closely related research findings from Logan [1] about substantial benefits of such referrals indicates that the CCDS is likely to generate worthwhile clinical benefits over a longer follow up period.

When the CCDS was implemented, quantitative and qualitative findings are encouraging in a context where the CCDS was implemented, due to circumstances, without full integration with electronic data capture, and with known limitations in usability. Patients, paramedics and
stakeholders within the ambulance and partner services were supportive of the intervention in principle, and the intervention did impact on paramedic practice, both when it was actively used, and more widely, in the group of paramedics trained in its usage.

With further development of usability, including integration with electronic data capture systems, which are evolving all the time in the UK prehospital emergency care setting, these results indicate that CCDS may provide a very useful tool to support paramedics in changing practice and benefitting patients.

Based on these results we recommend that further investment is made to develop CCDS for use in prehospital emergency care, to be more user-friendly, and to integrate the decision support software with other software designed to capture patient-related data at the scene of 999 calls. In particular we propose that integrated CCDS-ePRF systems are then tested for patients who have suffered falls or have other conditions that may not need immediate care at the ED, with appropriate piloting and then through further fully powered multi centred RCT, with ambulance and partner NHS services who are fully committed to delivering such a trial. In the meantime, evidence about the cost–effectiveness of training, paper-based protocols and access to falls referral pathways is being gathered through a parallel multi centred NIHR HTA funded trial, SAFER 2.

In short, given the evidence that CCDS does not put patients at risk, and its low cost, we judge that the resulting increase in referrals to falls services is likely to benefit older people who fall and yield value for money.
References

Appendices

Appendix 1  Literature Review
Appendix 2  Pilot Data Collection Report
Appendix 3  Data Flow Diagram
Appendix 4  Questionnaire
Appendix 5  Questionnaire Responses from Patients
Appendix 6  Service User Involvement
Appendix 7  Interview Guides
Appendix 8  Information Sheet
Appendix 9  Systematic Review Search Terms
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Appendix 1  Face-to-face computerised clinical decision support (CCDS) use in the emergency and unscheduled care setting: a systematic review of effects on processes and outcomes

ABSTRACT

Aim
To identify and describe the existing evidence in relation to face-to-face computerised clinical decision support (CCDS) use in the emergency and unscheduled care setting: a systematic review of effects on processes and outcomes

Design
Systematic review

Data sources
8 electronic databases (CINAHL, PubMed, HMIC, Cochrane, Web of Science, BNI, Intute, NHS Evidence), searches of reference lists of included studies, materials previously collated by the authors

Study selection
Peer-reviewed, evaluative/comparative studies where face-to-face CCDS tools were used by healthcare professionals in the emergency and unscheduled healthcare setting to support decision making about individual patient care. Published between Jan 2000 and Dec 2010

Data extraction
Data was extracted on study and intervention characteristics, participants under evaluation, patient numbers, performance outcomes, patient outcomes, implementation issues and adoption issues.

Results
1202 references were identified by the library and supplementary search. No prior systematic review of CCDS use in the emergency or unscheduled healthcare setting was identified. 20 studies were identified for inclusion in this review.

Conclusions
There was a focus on processes of care/practitioner performance in 19 of the 20 studies in this review. However, patient outcomes were not widely reported on and there was very little evidence related to the impact of CCDS on patient outcomes; what did exist was inconsistent and unclear. It is important that future research in this area doesn’t continue to overlook the relationship between CCDS and improving patient care. This review highlights that although face to face CCDS research is being undertaken in the emergency and unscheduled care setting, the evidence that is emerging is as yet inconclusive and lacking, particularly with regard to patient outcomes.
INTRODUCTION

Against a backdrop of ongoing reform, the NHS in England and Wales faces increasing demand on finite resources. Strategies are being put in place to improve the efficiency and effectiveness of care for the patient. Technology is also being used to modernise the NHS and bring new opportunities for both caregivers and patients to use data innovatively to enhance service development and delivery. For example, in the ambulance service hand-held computers are being rolled out to paramedics to collect patient data electronically rather than on paper.

As technologies become more widely used in the healthcare setting generally, the opportunities for software to enhance service delivery are being explored, for example through the development of computerised clinical decision support software (CCDS). CCDS software is designed to assist healthcare professional make decisions about patient care. In essence, patient-related information is entered into a software package that then generates information and guidance related to the patient. The healthcare practitioner can then use this information to support their clinical decision making, for example with triage assessment to support or to reduce prescription errors [1, 2].

CCDS technology represents the next step in enhancing the functionality of software designed for use by paramedics and presents a number of potential benefits. These include; the potential to increase skill-mix through supporting and up-skilling staff; the opportunities associated with new information and communications technologies; increased clinical governance and expectations for consistency and reliability of care; risk of error and healthcare, managerial and legal costs associated with mitigation of error, including litigation associated with complaints, and auditable records of care.

Previous key systematic reviews on CCDS in healthcare [3,4] have identified that there is often unclear or inconsistent evidence regarding the efficacy of CCDS in relation to practitioner performance and patient outcomes. This study will build on previous reviews of CCDS in healthcare, but with a specific focus on face to face CCDS in the emergency and unscheduled care setting.

**Aim and objectives**

It is the aim of this systematic review to identify and describe the existing evidence in relation to face-to-face use of CCDS in the emergency and unscheduled care setting, focusing on the implementation and adoption of face-to-face CCDS by healthcare professionals and to assess its effect on practitioner performance and processes of care.

Objective 1: What was the methodological quality of the papers in this review?

Objective 2: What face-to-face CCDS initiatives have been implemented in the emergency and unscheduled care setting?

Objective 3: How did CCDS impact on processes of care (practitioner performance)?

Objective 4: How did CCDS impact on patient outcomes?

Objective 5: What implementation issues were reported?

Objective 6: What adoption issues were reported?
METHODS

Search strategy

Searches for research literature were carried out in eight electronic databases (CINAHL, PubMed, HMIC, Cochrane, Web of Science, BNI, Intute, NHS Evidence) covering the period Jan 2000 to Dec 2010. A full list of the search terms used can be found in Appendix 8. We also reviewed the reference lists of included studies, relevant systematic reviews, key policy documents and materials previously collated by the authors.

Inclusion and exclusion criteria

Published, peer-reviewed, evaluative/comparative studies where face-to-face CCDS tools were used by healthcare professionals in the emergency and unscheduled healthcare setting. We defined evaluative studies as those which evaluated data in relation to CCDS interventions.

The time-frame covered by the review is Jan 2000 to Dec 2010 to cover the period since the NHS Plan was adopted in 2000. The search was limited to articles published in English.

For this review CCDS was defined as “any electronic system designed to aid directly in clinical decision making, in which characteristics of individual patients are used to generate patient-specific assessments or recommendations that are then presented to clinicians for consideration” in line with the definition used by Hunt et al (1998) [3].

Table 1: the PICOS (population, intervention, comparison, outcomes, study design) table, as devised by the Cochrane Collaboration for healthcare reviews. This sets out the inclusion and exclusion criteria in full.

<table>
<thead>
<tr>
<th>Population</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td></td>
<td>Emergency (999 &amp; ED) and unscheduled (unplanned) care setting</td>
<td>Intensive care or other setting</td>
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<tr>
<td>Intervention</td>
<td>Face to face CCDS used</td>
<td>CCDS not face to face</td>
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<td></td>
<td>Computerised clinical decision support</td>
<td>Paper based clinical decision support</td>
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<td></td>
<td>CCDS used in patient care, not for learning, training or product development purposes</td>
<td>CCDS used for learning, training or product development purposes</td>
</tr>
<tr>
<td></td>
<td>The CCDS assessment provides healthcare professionals with individualised recommendations for follow-on patient care</td>
<td>CCDS assessment provides no recommendation or not individualised</td>
</tr>
<tr>
<td>Comparison</td>
<td>Comparative data</td>
<td>Simulated application</td>
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</tbody>
</table>
### Inclusion criteria

<table>
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<tr>
<th>Outcomes</th>
<th>Exclusion criteria</th>
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<tr>
<td>Objective 1: methodological quality</td>
<td></td>
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<tr>
<td>Objective 2: CCDS initiatives</td>
<td></td>
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<tr>
<td>Objective 3: processes of care</td>
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<td>Objective 4: patient outcomes</td>
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<td>Objective 5: implementation issues</td>
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<tr>
<td>Objective 6: adoption issues</td>
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</table>

### Exclusion criteria

### Study design

- Evaluative/comparative (both qualitative and quantitative)

### Study selection

Two researchers independently conducted an initial screening of abstracts identified in the search using the inclusion/exclusion criteria (table 1) and then worked together to achieve consensus on the list of papers to be acquired in full for second stage screening. Two researchers independently conducted the second stage screening using the inclusion/exclusion criteria table in relation to the full papers identified at initial screening and then worked together to achieve consensus on those eligible for inclusion in the systematic review. An Endnote database was used to manage references.

### Data extraction

There were three researchers in the data extraction team, 15 of the 20 studies selected for inclusion in the review were independently data extracted by two researchers, the other five were data extracted by the lead researcher only. Data were extracted in relation to study and intervention characteristics, participants under evaluation, patient numbers, practitioner performance outcomes, patient outcomes, implementation issues and adoption issues onto a spreadsheet designed (and piloted) for this review. Discrepancies were resolved by the lead researcher where possible and by discussion where necessary.

### Quality assessment

A full quality assessment of the studies included in this review will be undertaken and included in the paper prior to its publication. Papers will be assessed to a) classify them according to the Oxford Centre for Evidence-based Medicine; and b) rate the quality of comparative studies using the checklist developed by Lewis et al [5] based on the checklist by Downs and Black [6]. 15 of the studies will be reviewed by one researcher and the other five will be reviewed by two researchers. Papers for review by two researchers were selected based on a systematic sampling of one in four studies from a random starting point.
**Data synthesis**

A narrative synthesis was undertaken for this review. The approach used was adopted from the York Centre for Reviews and Dissemination [7] guidance on undertaking systematic reviews in healthcare, which in turn was derived from the Economic and Social Research Council ref guidance on conducting narrative synthesis in systematic reviews. The guidance proposes the following framework:

- Developing a theory of how the intervention works, why and for whom
- Developing a preliminary synthesis of findings of included studies
- Exploring relationships within and between studies
- Assessing the robustness of the synthesis

**RESULTS**

Overall, 1202 references were identified by the library and supplementary search, of which 77 were identified by two researchers as being potentially eligible on the basis of their title and abstract. Five of these were not located and therefore were not considered further. Second stage screening of the full reports by two researchers led to 52 shortlisted papers being excluded, leaving 20 studies identified for inclusion in this review. No prior systematic review of CCDS use in the emergency or unscheduled healthcare setting was identified, thus confirming the scientific justification for conducting this review.

**Figure 1: Flowchart of papers identified and included/excluded at each stage**

1. References retrieved by search (n=1202)
2. Excluded at 1st screening (n=1125)
3. Potentially eligible references (n=77)
4. Full reports obtained (n=72)
5. Excluded at 2nd screening (n=51)
6. Included in review (n=20)

**Description of studies**

The 20 studies included more than 19,000 patients and were carried out in seven countries (eight from the US, six from Canada, two from Australia and one each from the UK, France, Italy and the Netherlands). Five of these were Randomised Controlled Trials (RCTs), one was a Cluster-RCT, one described itself as a ‘clinical trial’ and another as a ‘validation trial’. Five of the studies were cohort studies, five were observational studies and one was based on qualitative interviews. The remaining study described itself as a comparison study.
The setting for all but one of the papers in this review was emergency care departments. The remaining study was set in an NHS Walk-in centre.

The papers covered CCDS application for a wide range of conditions including asthma, pneumonia, stroke, abdominal pain, chest pain, fever in children, pulmonary embolism, thrombolysis and to increase flu vaccine uptake. The CCDS in the remaining studies was used to support triage, diagnosis, dosing levels and prescribing.

**Objective 1: Methodological quality**

The quality assessment of papers is ongoing.

**Objective 2: CCDS initiatives**

The CCDS initiatives in this review were conducted on Personal Computers, hand-held computers, and laptops. In all but one of these initiatives the healthcare practitioner completed the CCDS. In one study the parents input data relating to their children on a multi-language, multi-media touch screen device and the output was made available to the healthcare practitioner.

A summary of the papers included in this review is given in table 1 below.
<table>
<thead>
<tr>
<th>Study refs (+ country)</th>
<th>Study type</th>
<th>No of sites</th>
<th>Participants (ie those under evaluation)</th>
<th>No patients</th>
<th>Intervention &amp; setting</th>
</tr>
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<tbody>
<tr>
<td>Brown et al 2007 Implementation of an ED based transient ischemic attack clinical pathway: a pilot study (US) [1*]</td>
<td>prospective cohort study (pilot)</td>
<td>1</td>
<td>30 ED residents and 35 doctors</td>
<td>75</td>
<td>A CCDS clinical pathway to support physicians evaluating and discharging stroke patents from the ED. Community hospital ED</td>
</tr>
<tr>
<td>Buisings et al 2008 Improving antibiotic prescribing for adults with community acquired pneumonia (Australia) [2*]</td>
<td>pre and post cohort study</td>
<td>1</td>
<td>ED Doctors (both senior and junior medical staff)</td>
<td>348</td>
<td>CCDS compared to educating Drs to improve antibiotic prescribing for children with diagnosed with pneumonia in ED. Urban adult tertiary teaching hospital ED</td>
</tr>
<tr>
<td>Bullard et al 2004 Supporting clinical practice at the bedside using wireless technology (Canada) [3*]</td>
<td>RCT</td>
<td>1</td>
<td>ED doctors</td>
<td>1500-2500</td>
<td>Examined the use of a wirelessly networked mobile computer (MC) by physicians at the bedside with access to an emergency department information system, decision support tools (DSTs), and other software options. Academic tertiary care ED</td>
</tr>
<tr>
<td>Dong et al 2005 Emergency triage: Comparing a novel computer triage program with standard triage (Canada) [4*]</td>
<td>Prospective observational study</td>
<td>1</td>
<td>37 ED triage nurses</td>
<td>722</td>
<td>Comparing nurses conducting ED triage from memory with nurses conducting CCDS based triage. Etriage won as its triage scores were closer to that of the expert panel. Urban tertiary care teaching hospital ED</td>
</tr>
<tr>
<td>Dong et al 2006 Reliability of computerised emergency triage 2006 (Canada) [5*]</td>
<td>Prospective observational study</td>
<td>1</td>
<td>8 ED triage nurses and 2 study nurses</td>
<td>569</td>
<td>Comparing interrater reliability of CCDS triage scores between triage nurses (2 nurses triaged each patient). Urban tertiary care teaching hospital ED</td>
</tr>
<tr>
<td>Dong et al 2007 The effect of training on nurse agreement using an electronic triage system (Canada) [6*]</td>
<td>Prospective cohort</td>
<td>1</td>
<td>77 triage nurses</td>
<td>1068</td>
<td>Comparing interrater reliability of CCDS triage scores between triage nurses with different levels of CCDS tool training. Urban tertiary care teaching hospital ED</td>
</tr>
<tr>
<td>Dowding et al 2009 Nurses’ use of computerised clinical decision support systems: a case site analysis (UK) [7*]</td>
<td>multiple case site study - qualitative methods</td>
<td>4</td>
<td>Nurses</td>
<td>115</td>
<td>Interviewing nurses to explore how they use CCDS in clinical practice and the factors that influence this. Four case study sites were used, one of these was a walk-in centre using CCDS to support patient assessment.</td>
</tr>
<tr>
<td>Farion et al 2008 Prospective evaluation of the MET-AP system providing triage plans for acute pediatric abdominal pain (Canada) [8*]</td>
<td>Prospective validation trial</td>
<td>1</td>
<td>ED doctors and residents</td>
<td>574</td>
<td>Comparing triage accuracy of emergency physicians and residents against a CCDS triage tool as rated against a study generated gold-standard for children presenting to ED with acute abdominal pain. Tertiary care pediatric ED</td>
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<tr>
<td>Study refs (+ country)</td>
<td>Study type</td>
<td>No of sites</td>
<td>Participants (ie those under evaluation)</td>
<td>No patients</td>
<td>Intervention &amp; setting</td>
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<tr>
<td>Graber &amp; VanScoy 2003 How well does decision support software perform in the ED? (USA) [9*]</td>
<td>Prospective comparison</td>
<td>1</td>
<td>ED physicians</td>
<td>25</td>
<td>Comparing effectiveness of CCDS in ED (where patient data available isn’t as comprehensive as in other settings) against final diagnoses of ED attending. Tertiary care academic medical centre ED</td>
</tr>
<tr>
<td>Gravel et al 2008 Interrater agreement between nurses for the Pediatric Canadian Triage Acuity in a tertiary care centre (Canada) [10*]</td>
<td>Prospective cohort study</td>
<td>1</td>
<td>ED triage nurses</td>
<td>499</td>
<td>Comparing interrater reliability between 2 nurses using a CCDS triage and acuity tool to assess children not needing immediate care. Tertiary care pediatric hospital ED</td>
</tr>
<tr>
<td>Kwok et al 2009 Improving adherence to asthma clinical guidelines and discharge documentation from EDs (Australia) [11*]</td>
<td>Pre and post implementation observational study</td>
<td>1</td>
<td>ED doctors</td>
<td>100</td>
<td>Comparing patient assessments by ED physicians both pre and post implementation of CCDS tool for clinical assessment of asthma Metropolitan hospital ED</td>
</tr>
<tr>
<td>Lorenzoni et al 2006 A computer protocol to evaluate subjects with chest pain in the ED (Italy) [12*]</td>
<td>Prospective observational study</td>
<td>7</td>
<td>Patients presenting at ED with chest pain</td>
<td>472</td>
<td>Assessment of a CCDS triage tool for evaluating patients presenting to an ED with chest pain of uncertain origin (to identify coronary and non coronary diagnosis). 13 hospitals in Tuscany with an ED and a coronary care unit</td>
</tr>
<tr>
<td>Porter et al 2006 Impact of patient-centred decision support on quality of asthma care in the ED (US) [13*]</td>
<td>Clinical trial</td>
<td>1</td>
<td>Parents of children presenting to ED with asthma</td>
<td>286</td>
<td>Assessment of the impact of a CCDS tool for children presenting to ED with asthma. Parents complete the CCDS and clinicians receive a tailored plan of action from it. Tertiary care pediatric ED.</td>
</tr>
<tr>
<td>Roukema 2008 Randomised trial of a decision support system; impact on the management of children with fever without apparent source (Netherlands) [14*]</td>
<td>Randomised trial</td>
<td>1</td>
<td>ED nurses</td>
<td>164</td>
<td>Assessment of the impact of a CCDS tool for diagnostic management of children with fever without apparent source. Pediatric ED</td>
</tr>
<tr>
<td>Roy et al 2009 A computerised handheld decision-support system to improve pulmonary embolism diagnosis: a randomised trial (France) [15*]</td>
<td>Cluster randomised controlled trial</td>
<td>20</td>
<td>ED doctors</td>
<td>1645</td>
<td>Assessment of impact of hand-held CCDS for diagnosing pulmonary embolism in ED on doctors’ diagnostic decision making. 20 EDs</td>
</tr>
<tr>
<td>Sard et al 2008 Retrospective evaluation of a computerised physician order entry adaptation to prevent prescribing errors in a pediatric ED (US) [16*]</td>
<td>Retrospective cohort study</td>
<td>1</td>
<td>ED Drs (7), Fellows (4) and residents (130)</td>
<td>840</td>
<td>Assessment of impact on medication prescribing errors of adding a CCDS medication ‘quicklist’ to a computerised physician order entry system in a pediatric ED</td>
</tr>
<tr>
<td>Study refs (+ country)</td>
<td>Study type</td>
<td>No of sites</td>
<td>Participants (i.e., those under evaluation)</td>
<td>No patients</td>
<td>Intervention &amp; setting</td>
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</tr>
<tr>
<td>Selker 2002 Use of the electrocardiograph-based thrombolytic predictive instrument to assist thrombolytic and reperfusion therapy for acute myocardial infarction (US) [17*]</td>
<td>Multicentre randomised controlled clinical effectiveness trial</td>
<td>28</td>
<td>Persons 35+ presenting to ED with AMI and ST-segment elevation on an electrocardiogram</td>
<td>1197</td>
<td>To test whether an electrocardiograph-based CCDS tool (the Thrombolytic Predictive Instrument) improves use of thrombolytic and overall reperfusion therapy. 28 EDs in urban, suburban and rural hospitals in the US</td>
</tr>
<tr>
<td>Terrell et al 2009 Computerised decision support to reduce potentially inappropriate prescribing to older ED patients: a randomised controlled trial (US) [18*]</td>
<td>RCT</td>
<td>1</td>
<td>63 ED doctors</td>
<td>5162</td>
<td>Computer-assisted decision support designed to reduce prescribing of medications that are potentially inappropriate for older adults. Academic hospital ED</td>
</tr>
<tr>
<td>Terrell et al 2010 Computerised decision support for medication dosing in renal insufficiency: a randomised controlled trial (US) [19*]</td>
<td>Randomised, controlled trial</td>
<td>1</td>
<td>42 ED doctors and residents</td>
<td>2783</td>
<td>CCDS to facilitate the appropriate dosing of medications for adult patients with renal insufficiency who were being discharged home from the ED. Academic hospital ED</td>
</tr>
<tr>
<td>Venkat et al 2010 Feasibility of integrating a clinical decision support tool into an existing computerised physician order entry system to increase seasonal influenza vaccination in the ED (US) [20*]</td>
<td>prospective, observational trial</td>
<td>1</td>
<td>ED patients</td>
<td>2270</td>
<td>Integrating a clinical decision support tool into an existing ED computerised physician order entry system in order to increase influenza vaccination uptake. Urban tertiary care centre ED</td>
</tr>
</tbody>
</table>
Objective 3: impact on processes of care (practitioner performance)

This section covers the impact of CCDS on processes of care/practitioner performance. 19 of the studies in this review contained process of care outcome measures. Three main processes of care measures were identified:

1) Adherence (or compliance) studies – these measure the extent to which practitioners adhere to the recommendations of the CCDS output
2) Concordance (or agreement) studies - these measure the extent to which CCDS and practitioners’ diagnoses agree with each other
3) Adoption studies – these explore the way in which the CCDS is used and are reported on under ‘Objective 6’

Nine of these studies focused on adherence; five on concordance; two on both adherence and concordance; two on adoption and one focused on both adherence and adoption.

Adherence to CCDS recommendations was measured in relation to the following: prescribing, triage, treating (giving medication, giving therapy, vaccination) and ordering lab tests. Nine papers reported a positive outcome with regard to practitioners adhering to CCDS recommendations; one reported a non-significant difference (prescribing rates for children with asthma) and three papers simply described issues related to adherence [8, 9, 10]. All three of these papers discussed how and why triage nurses overrode the CCDS triage recommendation.

Concordance related to CCDS use was assessed in relation to: triage of adults and children (n=5), diagnosis (n=1), documentation and discharge planning for asthma patients (n=1). Concordance was measured in the following ways:

- Between nurses using standard triage and others using CCDS
- Between two groups of nurses using CCDS
- Between Drs using CCDS against a study agreed standard triage
- Between CCDS and Dr diagnosis
- Between CCDS and Dr documentation and discharge plan

A summary of the findings in relation to adherence and concordance are contained in the Table 2 below:
<table>
<thead>
<tr>
<th>Study refs (+ country)</th>
<th>Intervention &amp; setting</th>
<th>Processes of care outcomes (practitioner performance)</th>
<th>Processes of care results</th>
<th>Patient outcomes (health / satisfaction related)</th>
<th>Patient outcome results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brown et al 2007</td>
<td>A CCDS clinical pathway to support physicians evaluating and discharging stroke patients from the ED. Community hospital ED</td>
<td>Drs adherence to CCDS pathway (triaging stroke patients)</td>
<td>Dr adherence to the clinical pathway (when used) was 85.3%. Only 75 subjects recruited to the study due to design flaws.</td>
<td>90-day risk of recurrent TIA, stroke, or death. Rate of uneventful hospitalization</td>
<td>Of the 75 subjects enrolled, 35 patients (46.7%) were discharged home from the ED. Antithrombotic agents were prescribed to 68 (90.7%), and vascular imaging was performed in 70 (93.3%).</td>
</tr>
<tr>
<td>Buisong et al 2008</td>
<td>CCDS compared to educating Drs to improve antibiotic prescribing for children with diagnosed with pneumonia in ED. Urban adult tertiary teaching hospital ED</td>
<td>Dr adherence to the CCDS pathway (appropriately prescribing children with pneumonia).</td>
<td>The CCDS improved prescribing practice more that training alone in the first month. Longer term study required to assess sustainability of this effect.</td>
<td>Not assessed</td>
<td>Not assessed</td>
</tr>
<tr>
<td>Bullard et al 2004</td>
<td>Examined the use of a wirelessly networked mobile computer (MC) by physicians at the bedside with access to an emergency department information system, decision support tools (DSTs), and other software options. Academic tertiary care ED</td>
<td>Adoption. Did they use it?</td>
<td>MCs were rated as being as fast and convenient as desk computers (DC). Overall, physicians rated MCs to be less efficient but encouraged more frequent use of CCDS tools without impacting doctor–patient communication. There were usability issues with the hardware (battery charging and carrying kit around)</td>
<td>Not assessed</td>
<td>Not assessed</td>
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<tr>
<td>Dong et al 2005</td>
<td>Comparing nurses conducting ED triage from memory with nurses conducting CCDS based triage. Etriage won as its triage scores were closer to that of the expert panel. Urban tertiary care teaching hospital ED</td>
<td>Concordance between nurse triage and CCDS (etriage)</td>
<td>Agreement between the two methods was poor. When compared with the expert panel, the nurse triage scores showed lower agreement (0.263; 95% CI = 0.133 to 0.394) than the CCDS triage (k = 0.426; 95% CI = 0.289 to 0.564). There was a significant down-triaging of patients when patients were triaged without the computerised tool.</td>
<td>Not assessed</td>
<td>Not assessed</td>
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<tr>
<td>Dong et al 2006</td>
<td>Comparing interrater reliability of CCDS triage scores between triage nurses (2 nurses triaged each patient). Urban tertiary care teaching hospital ED</td>
<td>Concordance between nurses using CCDS (etriage)</td>
<td>Agreement between the nurses was moderate if using linear k (weighted k = 0.52; 95% confidence interval = 0.46 to 0.57) and good if using quadratic k (weighted k=0.66; 95% confidence interval = 0.60 to 0.71).</td>
<td>Not assessed</td>
<td>Not assessed</td>
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<tr>
<td>Study refs (+ country)</td>
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<tr>
<td>Dong et al 2007 The effect of training on nurse agreement using an electronic triage system (Canada) [6*]</td>
<td>Comparing interrater reliability of CCDS triage scores between triage nurses with different levels of CCDS tool training. Urban tertiary care teaching hospital ED</td>
<td>Agreement between nurses trained for 3 hours (phase 1) compared with those who picked it up from colleagues (phase 2). Inter-rater agreement during phase 1 was moderate (weighted $\kappa = 0.55; 95%$ confidence interval [CI] 0.49–0.62); agreement improved in phase 2 (weighted $\kappa = 0.65; 95%$ CI 0.60–0.70). Manual overrides of eTRIAGE scores were infrequent (approximately 10%) during both periods (with a tendency to down triage)</td>
<td>Not assessed</td>
<td>Not assessed</td>
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<tr>
<td>Dowding et al 2009 Nurses’ use of computerised clinical decision support systems: a case site analysis (UK) [7*]</td>
<td>Interviewing nurses to explore how they use CCDS in clinical practice and the factors that influence this. Four case study sites were used, one of these was a walk-in centre using CCDS to support patient assessment.</td>
<td>Adoption: nurses report how they use CCDS (4 settings)</td>
<td>CCDS software was used to record information, monitor patients’ progress or confirm a decision that had already been made. They found that nurses a) integrate the CCDS knowledge and b) rely on it less as they become more experienced (at job/with software).</td>
<td>Not assessed</td>
<td>Not assessed</td>
</tr>
<tr>
<td>Farion et al 2008 Prospective evaluation of the MET-AP system providing triage plans for acute pediatric abdominal pain (Canada) [8*]</td>
<td>Comparing triage accuracy of emergency physicians and residents against a CCDS triage tool as rated against a study generated gold-standard for children presenting to ED with acute abdominal pain. Tertiary care pediatric ED</td>
<td>Concordance of Drs/residents using CCDS (etriage) against a gold standard triage plan for pediatric abdominal pain</td>
<td>For patient assessments by CCDS (n = 457), the recommendation was correct for 72% of patients (95% CI's: 67.9–76.1), while the physician’s prediction was correct in 70% of cases 65.9–74.2 (p = 0.518). However, the physicians’ triage plans were more conservative than those generated by CCDS, and a small number of patients whose triage plan should have been “consult surgery” would have been “discharged” by the CCDS tool. Inter-observer agreement on most attributes was moderate to near perfect.</td>
<td>Patient follow-up</td>
<td>Over 8 months, 574 patients with AP completed follow-up (10% appendicitis, 13% other pathology, 77% benign/resolving conditions).</td>
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<tr>
<td>Graber &amp; VanScoy 2003 How well does decision support software perform in the ED? (USA) [9*]</td>
<td>Comparing effectiveness of CCDS in ED (where patient data available isn’t as comprehensive as in other settings) against final diagnoses of ED attending. Tertiary care academic medical centre ED</td>
<td>Concordance of CCDS diagnosis with final ED diagnosis. Based on two CCDS softwares (Iliad and QMR)</td>
<td>The final ED diagnosis was found in the differential diagnosis generated by Iliad and QMR 72% and 52% of the time respectively. The final ED diagnosis was found in the top 10 diagnoses 51% and 44% of the time and in the top five diagnoses 36% and 32% of the time for each program respectively. This approximates to the performance of these programs in other clinical settings.</td>
<td>Not assessed</td>
<td>Not assessed</td>
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<tr>
<td>Gravel et al 2008 Interrater agreement between nurses for the Pediatric Canadian Triage Acuity in a tertiary care centre (Canada) [10*]</td>
<td>Comparing interrater reliability between 2 nurses using a CCDS triage and acuity tool to assess children not needing immediate care. Tertiary care pediatric hospital ED</td>
<td>1) concordance between nurses using CCDS (PedCTAS - etriage) 2) Adherence (overrides)</td>
<td>The overall interrater agreement was moderate (linear weighted kappa score of 0.55 [95% confidence interval CI = 0.48 to 0.61] and quadratic weighted kappa score of 0.61 [95% CI = 0.42 to 0.80]). There was a discrepancy of more than one level in only 10 patients (2% of the study population). Overrides occurred in 23.2 and 21.8% for regular and research triage nurses, respectively. These overrides were equally distributed between increase and decrease in triage level.</td>
<td>Not assessed</td>
<td>Not assessed</td>
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<tr>
<td>Study refs (+ country)</td>
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<tr>
<td>Kwok et al 2009</td>
<td>Improving adherence to asthma clinical guidelines and discharge documentation from EDs (Australia) [11*]</td>
<td>Comparing patient assessments by ED physicians both pre and post implementation of CCDS tool for clinical assessment of asthma Metropolitan hospital ED</td>
<td>Concordance between Drs’ use of traditional and CCDS (ACAFE) documentation/dischARGE planning</td>
<td>Use of CCDS was associated with significantly higher rates of documentation of asthma severity (98% vs 18%, p&lt;0.01), as well as other clinically important variables such as asthma precipitants, intensive care admission history and smoking history. ACAFED was also associated with significantly higher rate of asthma discharge plan documentation (76% vs 16% p&lt;0.01).</td>
<td>Not assessed</td>
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<tr>
<td>Lorenzoni et al 2006</td>
<td>A computer protocol to evaluate subjects with chest pain in the ED (Italy) [12*]</td>
<td>Assessment of a CCDS triage tool for evaluating patients presenting to an ED with chest pain of uncertain origin (to identify coronary and non coronary diagnosis). 13 hospitals in Tuscany with an ED and a coronary care unit</td>
<td>Not assessed</td>
<td>Not assessed</td>
<td>Not assessed</td>
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<tr>
<td>Porter et al 2006</td>
<td>Impact of patient-centred decision support on quality of asthma care in the ED (US) [13*]</td>
<td>Assessment of the impact of a CCDS tool for children presenting to ED with asthma. Parents complete the CCDS and clinicians receive a tailored plan of action from it. Tertiary care pediatric ED.</td>
<td>Adherence to CCDS prescribing recommendations for discharged patients (asthma patients)</td>
<td>The difference in number of appropriately treated patients was not significant between baseline and intervention. Physicians’ nonuse of kiosk generated recommendations may explain the limited impact of the intervention</td>
<td>The incidence of coronary events for patients defined by the protocol as being at low, medium-low, medium-high and high overall probability was 1.9, 12.8, 13.5 and 68.0%, respectively. The incidence of events was significantly higher in the high-probability patients than in the low and medium-probability patients and in the medium-probability patients than in the low-probability patients (P &lt; 0.05). However, the incidence of events was not different between patients in the medium-low and medium-high probability groups (P ¼ NS). The sensitivity and specificity of the CCDS protocol for established positive endpoints at 1 month was 90.4 and 86.8%, respectively; the predictive accuracy was 87.6%.</td>
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</table>

The number of reported information problems was unchanged between the baseline and intervention periods. When ED providers acted on kiosk data, reports of information problems were fewer (0.6 0.8) than when no action was taken (1.1 1.1). Most parents reported that they got as much information as they wanted during both periods (86% baseline, 85% intervention), but significantly more parents reported, “no,” at baseline than during intervention (12% vs 2%; P .001). The impact of the asthma kiosk was limited, with a notable negative effect on parents’ report of partnership with clinical providers.
<table>
<thead>
<tr>
<th>Study refs (+ country)</th>
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<tbody>
<tr>
<td>Roukema 2008 Randomised trial of a decision support system; impact on the management of children with fever without apparent source (Netherlands) [14*]</td>
<td>Assessment of the impact of a CCDS tool for diagnostic management of children with fever without apparent source. Pediatric ED</td>
<td>Drs adherence to CCDS recommendation s for lab tests (children with fever)</td>
<td>Compliance with registration of febrile children was 50% (683/1,399). Laboratory tests were significantly more frequently ordered in the intervention group (82%) than in the control group (44%, p = 0.001, 2 test).</td>
<td>To study the effects of application of the CCDS on time spent in the emergency department (ED)</td>
<td>Children in the intervention group had a median (25th–75th percentile) length of stay at the ED of 138 (104 – 181) minutes. The median length of stay at the ED in the control group was 123 (83–179) minutes. Children in the intervention group had a median (25th–75th percentile) length of stay at the ED of 138 (104–181) minutes. The median length of stay at the ED in the control group was 123 (83–179) minutes. The clinical decision rule, predicting whether children are at low or high risk for SBI, had a lower discriminative ability (AUC 0.56 (0.48–0.65)) than expected based on the validation study. The children whose lab tests were ordered immediately after nurse evaluation spent no shorter time in the ED than the children whose lab tests were reordered at the discretion of the attending physician.</td>
</tr>
<tr>
<td>Roy et al 2009 A computerised handheld decision-support system to improve pulmonary embolism diagnosis: a randomised trial (France) [15*]</td>
<td>Assessment of impact of handheld CCDS for diagnosing pulmonary embolism in ED on doctors’ diagnostic decision making. 20 EDs</td>
<td>1) Adoption: Drs use of CCDS for diagnosis 2) adherence to CCDS re no of lab tests ordered (pulmonary embolism)</td>
<td>1) The proportion of patients who received appropriate diagnostic work-ups was greater during the trial than in the preintervention period in both groups, but the increase was greater in the computer-based guidelines group (adjusted mean difference in increase, 19.3 percentage points favoring computer-based guidelines [95% CI, 2.9 to 35.6 percentage points]; P = 0.023). 2) Among patients with appropriate work-ups, those in the computer-based guidelines group received slightly fewer tests than did patients in the paper guidelines group (mean tests per patient, 1.76 [SD, 0.98] vs. 2.25 [SD, 1.04]; P = 0.001).</td>
<td>Clinical outcomes at 3 months. The study was not powered to detect differences in patients’ clinical outcomes.</td>
<td>A total of 1362 (82.8%) patients completed follow-up. The frequency of possible and definite venous thromboembolic events in patients who were untreated because of a negative initial work-up was low, with no statistically significant differences between groups 7 in the computer-based guidelines vs. 9 in the paper guidelines group; odds ratio, 0.9 [Cl, 0.2 to 3.0]; P = 1.00). Definite thromboembolic events were observed in 2 of 375 (0.5%) patients in the computer-based guidelines group and 6 of 589 (1.0%) patients in the paper guidelines group (odds ratio, 0.52 [0.05 to 2.94]; P = 0.48). Twenty of the patients who received a diagnosis of pulmonary embolism in the paper guideline group died, compared with 4 in the computer guidelines group.</td>
</tr>
<tr>
<td>Sard et al 2008 Retrospective evaluation of a computerised physician order entry adaptation to prevent prescribing errors in a pediatric ED (US) [16*]</td>
<td>Assessment of impact on medication prescribing errors of adding a CCDS medication ‘quicklist’ to a computerised physician order entry system in a pediatric ED</td>
<td>Dr adherence to CCDS pathway (to reduce prescribing errors in pediatric ED)</td>
<td>The quicklist was used in 30% of the orders in the postintervention group. In this group, the error rate was 1.9 errors per 100 orders when the quicklist was used, compared with 18.3 errors per 100 orders when the list was not used. We found an overall reduction in medication prescribing errors of 55% after adapting our pediatric emergency CPOE system by introducing the quicklist. More importantly, the error rate was 10-fold less when medications were ordered by using the quicklist.</td>
<td>Not assessed</td>
<td>Not assessed</td>
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<tr>
<td>Study refs (+ country)</td>
<td>Intervention &amp; setting</td>
<td>Processes of care outcomes (practitioner performance)</td>
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<tr>
<td><strong>Selker 2002 Use of the electrocardiograph-based thrombolytic predictive instrument to assist thrombolytic and reperfusion therapy for acute myocardial infarction (US) [17]</strong></td>
<td>To test whether an electrocardiograph-based CCDS tool (the Thrombolytic Predictive Instrument) improves use of thrombolytic and overall reperfusion therapy. 28 EDs in urban, suburban and rural hospitals in the US</td>
<td>Drs adherence to the CCDS pathway (thrombolytic therapy rates)</td>
<td>CCDS increased use of thrombolytic therapy, use of thrombolytic therapy within 1 hour, and use of overall coronary reperfusion by 11% to 12% for patients with inferior AMI, 18% to 22% for women, and 30% to 34% for patients with an off-site physician. Although its effect was minimal on patients with high baseline reperfusion rates, the CCDS increased use and timeliness of reperfusion in often-missed groups and when involved physicians were off site.</td>
<td>This study was not powered to detect differences in patients' clinical outcomes. It monitored mortality and stroke rates for safety reasons.</td>
<td>Overall mortality rates were 3.4% in the control group and 5.0% in the TPI group (P 0.15). When these rates were corrected for the higher rate of diabetes in the TPI group, again, they did not differ significantly (P 0.2). Three strokes each (0.5%) occurred in the control and TPI groups (P 0.2). Thrombolysis-related bleeding requiring transfusion occurred in 16 controls (4.5%) and 22 patients in the TPI group (5.8%) (P 0.2).</td>
</tr>
<tr>
<td><strong>Terrell et al 2009 Computerised decision support to reduce potentially inappropriate prescribing to older ED patients: a randomised controlled trial (US) [18]</strong></td>
<td>Computer-assisted decision support designed to reduce prescribing of medications that are potentially inappropriate for older adults. Academic hospital ED</td>
<td>Adherence to CCDS pathway (prescribing for older people)</td>
<td>Computerised physician order entry with CCDS significantly reduced the proportion of ED discharges that resulted in a potentially inappropriate prescription (3.9% vs 2.6%; P=5.02; odds ratio (OR)50.55, 95% confidence interval (CI)50.34–0.89). This difference represents an absolute risk reduction of 1.3% (95% CI50.4–2.3%). When analyzed as a percentage of all medications prescribed by physician subjects, the proportion of medications that were potentially inappropriate was significantly reduced, from 5.4% to 3.4%</td>
<td>Not assessed</td>
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<tr>
<td><strong>Terrell et al 2010 Computerised decision support for medication dosing in renal insufficiency: a randomised controlled trial (US) [19]</strong></td>
<td>CCDS to facilitate the appropriate dosing of medications for adult patients with renal insufficiency who were being discharged home from the ED. Academic hospital ED.</td>
<td>Drs adherence to CCDS pathway (medication dosing in patients with renal insufficiency)</td>
<td>Computerised physician order entry with decision support significantly reduced excessive dosing of targeted medications. Decision support was provided 73 times to physicians in the intervention group, who excessively dosed 31 (43%) prescriptions. In comparison, control physicians excessively dosed a significantly larger proportion of medications: 34 of 46, 74% (effect size 31%; 95% confidence interval 14% to 49%; P .001).</td>
<td>Not assessed</td>
<td>Not assessed</td>
</tr>
<tr>
<td><strong>Venkat et al 2010 Feasibility of integrating a clinical decision support tool into an existing computerised physician order entry system to increase seasonal influenza vaccination in the ED (US) [20]</strong></td>
<td>Integrating a clinical decision support tool into an existing ED computerised physician order entry system in order to increase influenza vaccination uptake. Urban tertiary care centre ED</td>
<td>Drs adherence to CCDS pathway (delivery of seasonal influenza vaccination)</td>
<td>Compared to the pre-protocol period, ED influenza vaccination rose by 17.5% with CCDS, however, this finding was seriously confounded by an influenza and vaccination epidemic during the CCDS usage period.</td>
<td>Not assessed</td>
<td>Not assessed</td>
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</table>


Objective 4: impact on patient outcomes

Six of the papers in this review reported on patient related outcomes. Two found a positive impact on patient outcomes from using CCDS. Lorenzoni et al 2006 tested a CCDS for evaluating the severity of chest pain in ED. Discharged patients were followed up and a low incidence of cardiovascular events was found, demonstrating that the CCDS had supported practitioners in triaging patients presenting to the ED with chest pain appropriately, resulting in patients receiving appropriate care. Selker 2002 tested CCDS designed to assist thrombolytic and reperfusion therapy for acute myocardial infarction. The study found that although the intervention had minimal effect in patient groups with already-high rates of reperfusion, it increased and expedited use of thrombolytic and overall reperfusion therapy for patients typically treated less often or less quickly.

Two of the studies had unexpected or negative findings. Porter et al 2006 tested an ‘asthma kiosk’, a CCDS tool that parents completed themselves in the ED for their asthmatic children. It produced a tailored plan of action for use by clinical providers. The primary outcomes were patient satisfaction with care (investigated during follow-up telephone interviews with the parents). The output from the parent-completed CCDS was available to practitioners but was frequently not used by them and this had a negative impact on parents’ satisfaction. Conversely, when the CCDS recommendations were used by the clinician the impact on satisfaction was positive. Roukema 2008 implemented a CCDS for diagnostic management of young children with fever without apparent source. The CCDS was successful with regard to compliance and adherence to CCDS recommendations. However, as it had unexpected negative effects on patient outcome in terms of ED length of stay and number of laboratory tests, its use was subsequently discontinued.

One study, Dong et al 2007, compared a CCDS triage scores with cost of care and patient deaths. The study follow-up identified a positive correlation between severity score, cost of care and patient mortality. Finally, a study by Brown et al 2007 that was designed to assess whether CCDS could be used to assess and discharge stroke patients from ED safely and efficiently failed to recruit adequately due to flaws in the study design.

Objective 5: implementation issues

For the purpose of this review ‘implementation issues’ relate to setting up the intervention, hardware installation and software development.

Three of the papers in this review reported on implementation issues, this tended to be when serious problems that adversely affected the study had been encountered. Implementation issues included problems with the software not being sufficiently developed or sophisticated [11]. Sometimes algorithms would produce a result that did not take into account the full information available, for example in the study by Graber and Vanscoy (2003) the ability to input the duration of signs and symptoms was limited and the CCDS programme was unable to account for the sequence of symptom development. It also didn’t allow data to be entered that was beyond its own limited vocabulary. It is possible that sometimes underdeveloped software packages are trialled, which may bias the outcomes.

Other implementation issues reported included a study where patients were not being recruited by practitioners, this was attributed to both flaws in the study set up and the additional demands of practitioners having to identify and register eligible patients to the trial in a busy ED [12]. In another study the use of a CCDS tool to increase the number of seasonal flu vaccinations administered was halted by a flu epidemic during the intervention period [11].
**Objective 6: adoption issues**

For the purpose of this review ‘adoption issues’ relate to the hands-on use or non-use of CCDS. Issues relating to CCDS usage were reported in 11 of the papers included in this review.

Three studies focussed on adoption issues. Bullard et al (2004) recruited Drs to use CCDS with a wireless link to an ED information system. Although the Drs were positive about these tools there were usability issues (e.g. battery charging and carrying kit). Dowding et al (2009) reported on how nurses used CCDS (based on interviews) and found that they used it to record information, monitor patients’ progress or confirm a decision that had already been made. They found that nurses a) integrate the CCDS knowledge and b) rely on it less as they become more experienced (at job/with software). The nurses also reported learning how to use the software to get the outcome they felt was appropriate. Finally, Roy et al (2009) tested a CCDS to improve pulmonary embolism diagnosis and found that it had a positive impact on the number of patients receiving appropriate diagnostic work-ups.

In several studies CCDS usage levels were low which caused problems for the research teams involved. For example, in one instance a trial was reduced to the status of a pilot because of the low levels of physician usage of the CCDS [12]. Other studies that reported low usage levels included Sard et al 2008, Roukema et al 2008, Porter et al 2006, Farion et al 2008. The reasons given for the problems encountered varied, but included; problems maintaining engagement, busy periods in the ED that detracted from using the software. Other adoption issues raised included; practitioners reporting that CCDS took too long to use to be useful, practitioners reporting software inadequacies (e.g. lack of appropriate algorithms, inflexibility of algorithms), and that the equipment could be cumbersome.

**DISCUSSION**

**CCDS initiatives**

The main focus of the papers in this review was on practitioner performance/processes of care rather than patients outcomes, a finding echoing that of Garg et al (2005). This perhaps reflects the early stage at which CCDS programme development is at in the field of emergency and unscheduled care. Importantly, it reinforces the need for CCDS research that addresses patient outcomes.

**Impact on processes of care/practitioner performance**

The main focus of CCDS research in this field is on processes of care. In general the studies could be categorised as addressing one or more of the following areas; adherence/compliance to CCDS recommendations, concordance or agreement between practitioner and CCDS diagnoses, and adoption (or use) of CCDS.

Issues that came up in relation to whether practitioners adhered to the CCDS recommendations of the CCDS included the approach taken to overrides (i.e. where a practitioner doesn’t adhere to the CCDS advice). In some studies when practitioners overrode the recommendation of the CCDS this was seen as a negative thing, compromising the delivery of the most appropriate care. In other studies the ability to override the CCDS recommendation was seen as being linked to higher level of experience and professionalism [8]. Across the studies overrides were reported as both a positive and negative thing, in some being reported as undesirable non-compliance and in others as a sign of experience and expertise; and it another the flexibility to allow overrides was reported as being a fundamental to its success. This raises questions over when overrides are acceptable, when they’re not and when they might be desirable.
Among the studies that evaluated concordance between CCDS and professional diagnosis it was interesting to find that studies varied greatly in terms of what was taken to be a measure of ‘correctness’. In some instances the CCDS was on test, its accuracy measured against the practitioner’s diagnosis, and sometimes it was the other way round, which raises the question; when does the CCDS recommendation carry more weight than that of the professional, and vice-versa? The consideration for those undertaking future research in this field is to clarify what is being measured, what it is being measured against, and what the clinical justification is for this approach.

**Impact on patient outcomes**

Of the six studies with a focus on patient outcomes, two reported a positive impact related to the use of CCDS, two had negative or ‘unexpected’ findings, one identified a correlation between CCDS triage score, cost of care and patient deaths and one study failed to recruit adequately.

From this review it is apparent that there is very little evidence regarding the impact of face to face CCDS use on patient outcomes in the field of emergency and unscheduled care. What little research there is provides inconsistent evidence relating to the impact of CCDS. Studies throughout this review fail to make clear the link between using CCDS and making a difference to patient care.

While this review highlights the paucity of quality research evidence in relation to face to face CCDS in the field of emergency and unscheduled care, it does it most starkly in relation to patient outcomes.

**Implementation issues**

Three papers reported on implementation issues, mainly in response to having encountered serious implementation problems. As implementation issues were not often reported this raises the question, do other studies encounter implementation issues but simply did not report on them? It is possible that many of these studies did not encounter significant implementation issues, however, conducting research in the field of emergency and unscheduled care is notoriously complex. Therefore it could be useful if the elements of these studies that were either addressed by the study team, or facilitated successful implementation, were reported on.

**Adoption issues**

Only three of the 20 studies in this review had a specific focus on adoption of CCDS as part of their study, eight others reported on adoption issues where they had encountered problems. The reasons for the problems included ease of use of the CCDS equipment, the time it took to complete CCDS, portability of equipment and practitioners that were disengaged or too busy.

The research in this review generally overlooked the opportunity to provide further evidence on the adoption element of CCDS initiatives. Adoption issues are so fundamental to the success or failure of these interventions that perhaps they should be reported on routinely in studies of this nature. This would ensure that both positive as well as negative methods and findings related to adoption are reported. Only by identifying what the adoption issues are in CCDS research can researchers and practitioners begin to meet the challenges of addressing them.

There were a couple of clear positive message in relation to adoption. These were that practitioners are more likely to use CCDS if it is incorporated into standard practice (rather than added-on). Also, for CCDS to be used by practitioners it has to work well and be acceptable to them.
**Strengths and weaknesses of this review**

We conducted a systematic review of the literature and identified 20 relevant evaluative/comparative studies for this paper, however it must be noted that the search was limited to studies reported on in English.

In order to provide an overview of the face to face CCDS initiatives being evaluated in the emergency and unscheduled care setting we chose to include a range of studies and did not limit the search to randomised controlled trials. This enabled us to meet the aim of providing a systematic overview of CCDS initiatives under evaluation in this care setting, but not to conduct a meta-analysis. A quality assessment of the 20 papers in this review is currently underway, the results of this will be used to inform a decision as to whether to take this review to the next stage, i.e. meta-analysis.

**CONCLUSIONS**

This review identified 20 studies of face-to-face CCDS in the emergency and unscheduled care setting. All but one of these were based in the emergency department and one in an NHS walk-in-centre. In general the studies could be categorised as addressing one or more of the following areas; adherence/compliance to CCDS recommendations, concordance or agreement between practitioner and CCDS diagnoses, and adoption (or use) of CCDS.

There was a focus on processes of care in 19 of the studies, yet patient outcomes were not widely reported on. There was very little evidence related to the impact of CCDS on patient outcomes, and what did exist was inconsistent and unclear. It is important that future research in this area doesn’t continue to overlook the relationship between CCDS and improving patient care.

Implementation issues were reported in a few of the studies identified, highlighting the need for well developed CCDS and the importance of engaging practitioners in the research. Adoption issues were reported regularly in relation to problems encountered during the research. However, despite their impact on the studies in this review, adoption and implementation issues were often reported as an ad hoc response to problems encountered, rather than routinely.

This review highlights that although face to face CCDS research is being undertaken in the emergency and unscheduled care setting, the evidence that is emerging is as yet inconclusive and lacking, particularly with regard to patient outcomes.
References


References for included tables


<table>
<thead>
<tr>
<th></th>
<th>Reference</th>
</tr>
</thead>
</table>
SAFER 1
Data Collection Processes Pilot

Final Report

30 September 2009

Gareth Thomas
Wai Yee Cheung
Helen Snooks
SAFER 1

Data Acquisition Pilot

Initial Findings

Introduction

In line with Medical Research Council guidance for RCT research\(^1\), it was agreed by all parties that a 'pilot' of the entire SAFER 1 data collection system be organised. The aim was to test and develop the processes of data collection and data transfer in order to better understand the quality of data and the flow of participants through the trial.

The objectives were to develop and test data collection processes and their timeliness:

- Identification of potentially eligible patients from command and control (dispatch) data
- Retrieval and matching with Patient Clinical Records (PCRs), completed by study paramedics at the scene of incidents in order to confirm eligibility of patients
- Sending out of ‘opt out’ letters
- Sending out of questionnaires and reminders
- Entry of data into the trial data management database
- Accuracy of data transfers between spreadsheets
- SAIL matching for anonymised follow up

The data collection processes pilot was undertaken at each of the two SAFER 1 trial sites: the Welsh Ambulance Service NHS Trust (WAST) and East of England Ambulance Service (EEAS). Results of the WAST pilot are reported here. The EEAS pilot is ongoing at the time of writing this report.

Methods- system development

It was agreed to gather data for one week starting 15 June 2009. Prior to the pilot several meetings were held with WAST and members of the study team in order to set up systems and agree processes. In addition to two face to face meetings, four telephone conferences between WAST and the research team were hosted by WAST.

\(^1\) Medical Research Council. A framework for the development and evaluation of RCTs for complex interventions to improve health. London: MRC 2000
Heightened sensitivity to patient confidentiality remained an issue throughout these meetings and resulted in a lengthy set of data collection and transfer processes as defined in the data acquisition protocol.

The following points were also resolved during this period:

- Agreement on information and introductory letters\(^2\):
- Translated Information sheet and introductory letters:
- Agreement on Opt Out Letter:
- Version of the V5 excel spreadsheet agreed:
- Data acquisition protocol updates:
- Freepost system for return of opt out letters

**Methods- system testing**

The entire system was tested for one week starting on Sunday 14 June at 11.59 and ending Monday 21st at 00.00.

A member of the Clinical Audit team logged onto the WAST internal website (intranet) daily and entered the agreed query to the command and control (dispatch) database. Clinical Audit staff have direct access to the command and control data and queries can be filtered by various parameters, such as paramedic code, AMPDS (Advanced Medical Priority Dispatch System) code and date. For the SAFER 1 trial Clinical Audit personnel filtered cases by dispatch code (AMPDS code 17), date, age and study paramedic pin code to gain the relevant incident number for potentially eligible patients. All patients identified as potentially eligible were entered onto a spreadsheet provided by a member of the Clinical Audit team. All entries on the spreadsheet have an outcome, and this was to be fed back to the team without any information that could identify individuals.

In parallel to this, during the pilot week, Patient Clinical Records (PCRs) completed by study paramedics that had been coded by call takers as Fall – no priority symptoms (AMPDS 17) were to be separated out and collated at each of the four participating WAST ambulance stations. A member of WAST staff was assigned to collect these and deliver them to the Clinical Audit team on a daily basis.

Once the cases identified by the query of command and control data had been matched to the paper PCR delivered from the stations it was verified by the Clinical Audit as meeting the trial inclusion criteria, or otherwise. Using the best address information from the command and control data or the PCR, the patient was then sent a letter of invitation to participate or opt out at 7 – 10 days by the Clinical Audit team member working on the trial. Reply slips were to be returned to the WAST

\(^2\) Letters were rewritten to reflect NIACE guidelines, this included the introduction of generic terms rather than jargon, smaller sentences, and simpler words. A readability test was conducted with the aim of bringing the reading age to 14. NIACE. *How to produce clear and written materials for a range of readers.* 2005 [http://shop.niace.org.uk/readability.html](http://shop.niace.org.uk/readability.html)
R&D Department. If no opt out form was received within the allotted 2 week period, a member of the study team hand collected paper copies of the PCRs, included in the study, from Conway House (Clinical Audit Department). This was done on 10 July 2009.

Study participants were sent a questionnaire by the study team with an explanatory letter on 13 July 2009. Reminder letters were sent 7 days later if no reply had been received.

Returned questionnaires were scanned into TeleForm by the study team. Questionnaire data from TeleForm populated an Excel (MS 2003) spreadsheet with the relevant data fields. All data fields were checked against the original questionnaire for errors. This spreadsheet was exported to SPSS (MS version 16) for analysis. All data fields and variables were checked for errors against the Excel (MS 2003) spreadsheet and the original questionnaires.

In order to test the pseudo-anonymised data linkage system for further follow up all of patients who had not opted out, first name, surname, gender, date of birth and postcode were supplied to the HIRU (Health Information Research Unit staff). These fields were used to attempt to match cases within the Secure Anonymised Information Linkage (SAIL)³ system which would allow further episodes of care to be identified for study patients. SAIL (Secure Anonymised Information Linkage) databank brings together the wide range of demographic and clinical anonymised person-based data. Each patient is allocated an Anonymous Linking Field (ALF) in place of the demographic data. An ALF takes the form of a unique 10-digit number assigned to each individual in a dataset. In some cases an exact match can be created, providing deterministic record linkage (DRL). However, it is more usual in complex datasets that some values are missing, and that unique identifiers are not present for all, if any, records. In these cases probabilistic record linkage (PRL) methods are used, taking account of the probabilities of agreement and disagreement between a range of matching variables.

Results

Recruitment of pilot participants, data linkage and response rates are shown in figure 1 which follows the CONSORT recommended flowchart style.\(^4\)

Thirty three people who were categorised as having fallen were identified from the Command and Control data. Twenty one PCRs were collected and matched to those fallers. Five of these were found not to match the study criteria (3 were out of the study area, 1 lived a nursing home, and 1 was under the age of 65) Two forms were only matched after the ten day period had passed and were not therefore further followed up. Three opt out reply slips were received by the Clinical Audit team. A further twelve PCRs were not collected by the operations team. Eleven PCR copies were picked up from the Clinical Audit department by the study team and 11 questionnaires were sent out. Four patients returned their questionnaires and after 1 reminder 1 more questionnaire was received.

All five questionnaires were fully completed without any apparent difficulties. All 5 returned questionnaires were scanned into TeleForm. The data, exported into an Excel (MS 2003) spreadsheet, in all five questionnaires, contained inaccuracies. When the TeleForm entries were compared to the original questionnaires question B2i, and B9c were particularly problematic because they require hand written numbers (number of times NHS services had been contacted and total amount of mileage for these journeys). When the Excel (MS 2003) spreadsheet was exported to SPSS (MS version 13), none of the data fields were recognised. A separate SPSS (MS version 13) spreadsheet was set up and then the data view was populated by cutting and pasting data from Excel (MS 2003). A member of the study team then checked all the data line by line.

Nine patients were matched through the SAIL databank with 5 of the patients matching in all the areas provided (ALF Status Code 4) with a very high level of certainty and 4 of the patients matching with a high level of certainty but with a known variant of the first name (ALF Status Code 39). 2 of the patients could not be matched at all (ALF Status Code 99). Both of the unmatched patients (with ID Num S1TP4, ID Num S1TP5) had invalid postcodes (ALF Status Code 99). This may explain why they were both non respondents to the questionnaire.
Table 1⁴. CONSORT Flow chart⁵ ⁶

Identified as potentially eligible: AMPDS 17, aged 65 or over, living within Swansea area, study paramedic, first time fallen within the study period (n=33)

Enrolment

Excluded (n=22)
Not meeting inclusion criteria (n=5)
(3 x out of area; 1x nursing home; 1x under age.)
Refused to participate (n=3)
PCR retrieved after >10 days (n = 2)
12 PCRs not collected

Eligible and consented (n=11)

SAIL matching (n=11)

Not matched (n=2)
Reason: postcode incorrect

Matched (n= 9)

Questionnaire sent (n= 11)

Matched (n= 9)

Questionnaire received (n= 5)

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⁴ The electronic version of the CONSORT E-Flowchart can be found online at: http://www.consort-statement.org/consort-statement/flow-diagram/


Data within WAST, from the Operations team to the Clinical Audit team, were not received on a daily basis, as defined in the data acquisition protocol, but arrived in sporadic bunches. This table shows those waves of data transfer. You will note from the table (column 1) that the PCRs came in two lots, although the incidents were spread out through the week (column 2). In effect this means that the entire process was delayed and in 2 cases it meant that the delay was such that the opt out letters were not sent. In 12 cases the PCRs were not received at all.

**Table 2: Waves of Data Arrival**

<table>
<thead>
<tr>
<th>Date PCR received</th>
<th>Incident date</th>
<th>Date ‘opt out’ Letters Sent out</th>
<th>Letter not sent</th>
<th>Opt out letter received</th>
<th>Included in study</th>
</tr>
</thead>
<tbody>
<tr>
<td>17/06/09</td>
<td>4x 15/06/09</td>
<td>4x 19/06/09</td>
<td>0</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>26/06/09</td>
<td>2x 17/06/09</td>
<td>3x24/06/09</td>
<td>1 x resident out of area</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Not received but collected on 26/06/09</td>
<td>2x 15/06/09</td>
<td>7x 26/06/09</td>
<td>2 x &gt;10 days 2x resident out of area 1x nurse home 1x under age</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Not received</td>
<td>Not known</td>
<td>Not sent</td>
<td>12x no PCR received – eligibility and address not verified</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>21 (64%)</td>
<td>14 (42%)</td>
<td>19 (60.6%)</td>
<td>3 (6%)</td>
<td>11 (33.3%)</td>
<td></td>
</tr>
</tbody>
</table>
Discussion

- Identification of potentially eligible patients from command and control (dispatch) data

The query of the command and control database was run according to the data acquisition protocol although fewer patients were identified than expected. The research team would like to explore this with the Clinical Audit team to identify any possible gaps in identification.

- Retrieval and matching with Patient Clinical Records (PCRs), completed by study paramedics at the scene of incidents in order to confirm eligibility of patients

Of the 33 cases identified only 19 PCRs were retrieved within the required timeframe. Two were retrieved later and 12 not at all. This was the most problematic part of the pilot. The 19 PCRs retrieved allowed verification of eligibility of patients in all cases.

- Sending out of ‘opt out’ letters

Opt out letters were sent out to all patients identified as eligible within the required timeframe. Three opt outs were received – a higher proportion than expected.

- Sending out of questionnaires and reminders

Questionnaires were sent out to all of the patients who had been sent opt out letters and who had not returned their opt out reply slips within the required timeframe.

- Entry of data into the trial data management database

Data were entered onto the trial data management database by the Clinical Audit team. Non-identifiable data needs to be returned to the research team for reporting purposes – this did not happen during the pilot.

- Accuracy of data transfers between spreadsheets

Problems were identified with data transfer that were resolved by transferring data direct to SPSS and by introducing a data checking step for hand written numbers.

- SAIL matching for anonymised follow up

A high proportion of cases were matched through the SAIL databank (9/11). The two other cases failed due to inaccurate or incomplete addresses, these will now be checked and returned for a further attempt at matching.

The problems experienced during the pilot were both at a data transfer and data validity level. On a data transfer level the delivery of PCRs to the Clinical Audit Department by the Operational staff was particularly problematic. The data acquisition protocol has now been altered to reflect this, a less senior staff member will pick up PCRs from one of four stations per day, rather than all four stations, per day. Transferring data from the Clinical Audit Department to Swansea University is time consuming. Paper PCRs have to be picked up by a member of the University staff and inputted into a separate spreadsheet by hand. However, as heightened sensitivity to patient confidentiality remains an issue this is unlikely to change.
On a data validity level, TeleForm should extract information automatically from any document type including questions with narrative and tick box answers. However, due to the problems we recognised we will be exporting data directly into SPSS. Additionally, all sections which contain written numbers (B2i, B9c, and B10c) will be checked by hand, after scanning into SPSS (MS version 16), by a member of the study team against the original questionnaire.

Using the process approved by the Multi Centre Research Ethics Committee (MREC) resulted in a low response rate from participants. The study team will approach the MREC to amend this process, with advice from the chair. We will ask for approval to either send out a second questionnaire to non-respondents or for the ambulance service to telephone non-respondents to remind patients or to complete the questionnaire by phone.

**Conclusion**

The data acquisition pilot proved to be a worthwhile exercise. Valuable information was gained in order to refine sample size estimates. Several areas of particular attention were highlighted with regard data transfer and data validity. The PCR collection system has been altered and the questionnaire response rate will need to be raised in order to increase the study participant numbers.

Due to the problems identified, a further pilot of data collection processes is required before the trial goes live. This will be undertaken alongside a pilot period for the intervention at each site, planned to take place for the first month of implementation.
Appendix 3 Data Flow Diagram
SAFER 1

ONE MONTH QUESTIONNAIRE

CONFIDENTIAL

dd mm yy yy yy

Date of questionnaire completion

Is someone completing this survey on your behalf
YES ☐ NO ☐

Please let us know their relationship to you

If you would like help with this questionnaire, please telephone 01792 513436

If there is no answer, please leave your details and a member of the SAFER team will return your call as soon as possible

Please return the completed questionnaire in the FREEPOST envelope provided.

THANK YOU
Please read the instructions carefully

- Use a blue or black pen, not a pencil
- Please mark your answers with an X clearly inside the box
- Answer every question
- If you find it difficult to answer a question, do the best you can.

SECTION A: 999 Care

This section asks about the care you received from the ambulance service on □ □ / □ □ / 20

A1. Overall, how would you rate your general health before this call?

   Excellent □   Good □   Fair □   Poor □   Very Poor □

A2. Do you feel the medical condition that you called 999 for was...

   Extremely Serious □   Moderately Serious □   Not Serious □

A3. Were the following acceptable:

   a) Wait time for the ambulance to arrive?
   □ Yes □ To some extent □ No □ Does not apply □

   b) Amount of time ambulance person spent with you?
   □ Yes □ To some extent □ No □ Does not apply □

   c) Decisions made by the person who attended you?
   □ Yes □ To some extent □ No □ Does not apply □

A4. Did you feel the ambulance person was concerned about you?
   □ Yes □ To some extent □ No □ Does not apply □

A5. Did you receive satisfactory answers to your questions from the ambulance person?
   □ Yes □ To some extent □ No □ Does not apply □
A6. Were any further referrals made by the ambulance person clearly explained to you?  ☐ ☐ ☐ ☐

A7. Were you satisfied with the thoroughness of the care you received?  ☐ ☐ ☐ ☐

A8. Overall, were you satisfied with the quality of care you received from the ambulance service?  ☐ ☐ ☐ ☐

A9. Overall, were you satisfied with the outcome of your 999 call?  ☐ ☐ ☐ ☐

SECTION B: Care and help needed
The next section asks questions about the care and help you may have needed following your 999 call.

B1. During the past month, how many times have you had a fall?

☐ No falls ☐ Once ☐ Twice ☐ Three times ☐ Four or more times

B2. Where are you living now?

Own Home ☐ Hospital In-patient ☐

Staying with Relatives ☐ Other ☐

Residential Home ☐ Please State ____________________________

B3. Where do you usually live?

Own Home ☐ Hospital In-patient ☐

Staying with Relatives ☐ Other ☐

Residential Home ☐ Please State ____________________________
SECTION C: Your health now

This section is about how you are feeling now and over the past 4 weeks.

C1. In general, would you say your health is:

Excellent ☐  Very Good ☐  Good ☐  Fair ☐  Poor ☐

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

<table>
<thead>
<tr>
<th></th>
<th>Yes, Limited</th>
<th>Yes, Limited</th>
<th>No, Not Limited</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A Lot</td>
<td>A Little</td>
<td>At All</td>
</tr>
</tbody>
</table>

C2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

C3. Climbing several flights of stairs

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

C4. Accomplished less than you would like

C5. Were limited in the kind of work or other activities

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

C6. Accomplished less than you would like

C7. Didn't do work or other activities as carefully as usual
C8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all □ Slightly □ Moderately □ Quite a bit □ Extremely □

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks:

<table>
<thead>
<tr>
<th></th>
<th>All of the Time</th>
<th>Most of the Time</th>
<th>A Good Bit of the Time</th>
<th>Some of the Time</th>
<th>A Little of the Time</th>
<th>None of the Time</th>
</tr>
</thead>
</table>

C9. Have you felt calm and peaceful?

C10. Did you have a lot of energy?

C11. Have you felt downhearted and blue?

C12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?
SECTION D: Fear of falling

This section is about how confident you are about being able to do things without falling.

Please circle your answer for each of the activities below, with 0 meaning "not confident at all", 5 meaning "fairly confident" and 10 meaning "completely confident".

<table>
<thead>
<tr>
<th>How confident are you that you can</th>
<th>Not confident at all</th>
<th>Fairly confident</th>
<th>Completely confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1. Get dressed and undressed</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D2. Prepare a simple meal</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D3. Take a bath or a shower</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D4. Get in/out of a chair</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D5. Get in/out of bed</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D6. Answer the door or telephone</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D7. Walk around the inside of your house</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D8. Reach into cupboards or wardrobes</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D9. Do light housekeeping</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D10. Do simple shopping</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D11. Use public transport</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D12. Cross roads</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D13. Do light gardening or hang out the washing (please rate whichever you do most frequently)</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D14. Using front or rear steps at home</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Thank you very much for your time and effort in completing this questionnaire.
# Appendix 5 Questionnaire Responses from Patients

## Section A: 999 Care

<table>
<thead>
<tr>
<th>Question</th>
<th>Excellent</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
<th>Very Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1. Overall, how would you rate your general health before this call</td>
<td>45</td>
<td>115</td>
<td>156</td>
<td>83</td>
<td>21</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Extremely Serious</th>
<th>Moderately Serious</th>
<th>Not Serious</th>
</tr>
</thead>
<tbody>
<tr>
<td>A2. Do you feel the medical condition that you called 999 for was...</td>
<td>98</td>
<td>233</td>
<td>85</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>To some extent</th>
<th>No</th>
<th>Does not apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>A3. Were the following acceptable:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Wait time for the ambulance to arrive?</td>
<td>373</td>
<td>14</td>
<td>15</td>
<td>5</td>
</tr>
<tr>
<td>b) Amount of time ambulance person spent with you?</td>
<td>388</td>
<td>12</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>c) Decisions made by the person who attended you?</td>
<td>387</td>
<td>10</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>A4. Did you feel the ambulance person was concerned about you?</td>
<td>392</td>
<td>18</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>A5. Did you receive satisfactory answers to your questions from the ambulance person?</td>
<td>367</td>
<td>9</td>
<td>2</td>
<td>34</td>
</tr>
<tr>
<td>A6. Were any further referrals made by the ambulance person clearly explained to you?</td>
<td>272</td>
<td>16</td>
<td>21</td>
<td>83</td>
</tr>
<tr>
<td>A7. Were you satisfied with the thoroughness of the care you received?</td>
<td>400</td>
<td>5</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>A8. Overall, were you satisfied with the quality of care you received from the ambulance service?</td>
<td>403</td>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>A9. Overall, were you satisfied with the outcome of your 999 call?</td>
<td>388</td>
<td>11</td>
<td>6</td>
<td>2</td>
</tr>
</tbody>
</table>
Section B: Care and help needed

<table>
<thead>
<tr>
<th>B1.</th>
<th>During the past month, how many times have you had a fall?</th>
<th>No falls</th>
<th>Once</th>
<th>Twice</th>
<th>Three times</th>
<th>Four or more times</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>164</td>
<td>107</td>
<td>78</td>
<td>31</td>
<td>31</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B2.</th>
<th>Where are you living now?</th>
<th>Own Home</th>
<th>Staying with Relatives</th>
<th>Residential Home</th>
<th>Hospital in-patient</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>315</td>
<td>15</td>
<td>16</td>
<td>34</td>
<td>29</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B3.</th>
<th>Where do you usually live?</th>
<th>Own Home</th>
<th>Staying with Relatives</th>
<th>Residential Home</th>
<th>Hospital in-patient</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>358</td>
<td>16</td>
<td>9</td>
<td>0</td>
<td>24</td>
</tr>
</tbody>
</table>

Section C: Your health now

<table>
<thead>
<tr>
<th>C1.</th>
<th>In general, would you say your health is:</th>
<th>Excellent</th>
<th>Very Good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>11</td>
<td>40</td>
<td>91</td>
<td>180</td>
<td>93</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C2.</th>
<th>Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</th>
<th>Yes, limited A Lot</th>
<th>Yes, Limited A Little</th>
<th>No, Not Limited At All</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>292</td>
<td>71</td>
<td>38</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C3.</th>
<th>Climbing several flights of stairs</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>264</td>
<td>67</td>
<td>43</td>
</tr>
<tr>
<td>C4.</td>
<td>Accomplished less than you would like</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>-----</td>
<td>-----------------------------------</td>
<td>-----</td>
<td>----</td>
<td></td>
</tr>
<tr>
<td>C5.</td>
<td>Were limited in the kind of work or other activities</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>C6.</td>
<td>Accomplished less than you would like</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>C7.</td>
<td>Didn’t do work or other activities <strong>carefully</strong> as usual</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C8.</th>
<th>During the <strong>past 4 weeks</strong> how much did <strong>pain</strong> interfere with your normal work (including both work outside the home and housework)?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All of the Time</td>
</tr>
<tr>
<td></td>
<td>Not at all</td>
</tr>
<tr>
<td>C9.</td>
<td>Have you felt calm and peaceful?</td>
</tr>
<tr>
<td>C10.</td>
<td>Did you have a lot of energy?</td>
</tr>
<tr>
<td>C11.</td>
<td>Have you felt downhearted and blue?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C12.</th>
<th>During the <strong>past 4 weeks</strong> how much of the time has your <strong>physical health or emotional problems</strong> interfered with your social activities (like visiting with friends, relatives, etc)?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All of the Time</td>
</tr>
<tr>
<td></td>
<td>153</td>
</tr>
</tbody>
</table>
## Section 4: Fear of Falling

<table>
<thead>
<tr>
<th>How confident are you that you can</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Get dressed and undressed</td>
<td>88</td>
<td>26</td>
<td>15</td>
<td>19</td>
<td>20</td>
<td>80</td>
<td>28</td>
<td>9</td>
<td>14</td>
<td>15</td>
<td>72</td>
</tr>
<tr>
<td>Prepare a simple meal</td>
<td>120</td>
<td>30</td>
<td>16</td>
<td>20</td>
<td>17</td>
<td>68</td>
<td>19</td>
<td>5</td>
<td>9</td>
<td>11</td>
<td>64</td>
</tr>
<tr>
<td>Take a bath or a shower</td>
<td>168</td>
<td>30</td>
<td>25</td>
<td>22</td>
<td>13</td>
<td>42</td>
<td>11</td>
<td>7</td>
<td>11</td>
<td>7</td>
<td>48</td>
</tr>
<tr>
<td>Get in/out of a chair</td>
<td>46</td>
<td>25</td>
<td>20</td>
<td>38</td>
<td>26</td>
<td>72</td>
<td>22</td>
<td>17</td>
<td>27</td>
<td>24</td>
<td>66</td>
</tr>
<tr>
<td>Get in/out of bed</td>
<td>59</td>
<td>27</td>
<td>24</td>
<td>26</td>
<td>27</td>
<td>72</td>
<td>20</td>
<td>18</td>
<td>22</td>
<td>22</td>
<td>68</td>
</tr>
<tr>
<td>Answer the door or telephone</td>
<td>85</td>
<td>15</td>
<td>21</td>
<td>19</td>
<td>18</td>
<td>58</td>
<td>18</td>
<td>17</td>
<td>34</td>
<td>19</td>
<td>74</td>
</tr>
<tr>
<td>Walk around the inside of your house</td>
<td>56</td>
<td>26</td>
<td>22</td>
<td>29</td>
<td>31</td>
<td>65</td>
<td>17</td>
<td>17</td>
<td>31</td>
<td>19</td>
<td>70</td>
</tr>
<tr>
<td>Reach into cupboards or wardrobes</td>
<td>100</td>
<td>32</td>
<td>19</td>
<td>29</td>
<td>22</td>
<td>58</td>
<td>17</td>
<td>9</td>
<td>20</td>
<td>18</td>
<td>55</td>
</tr>
<tr>
<td>Do light housekeeping</td>
<td>155</td>
<td>28</td>
<td>18</td>
<td>27</td>
<td>14</td>
<td>41</td>
<td>14</td>
<td>11</td>
<td>13</td>
<td>10</td>
<td>45</td>
</tr>
<tr>
<td>Do simple shopping</td>
<td>205</td>
<td>26</td>
<td>15</td>
<td>17</td>
<td>7</td>
<td>30</td>
<td>10</td>
<td>9</td>
<td>10</td>
<td>9</td>
<td>39</td>
</tr>
<tr>
<td>Use public transport</td>
<td>242</td>
<td>27</td>
<td>9</td>
<td>7</td>
<td>3</td>
<td>14</td>
<td>8</td>
<td>9</td>
<td>8</td>
<td>4</td>
<td>35</td>
</tr>
<tr>
<td>Cross roads</td>
<td>213</td>
<td>27</td>
<td>18</td>
<td>12</td>
<td>6</td>
<td>29</td>
<td>12</td>
<td>3</td>
<td>8</td>
<td>7</td>
<td>35</td>
</tr>
<tr>
<td>Do light gardening or hang out the washing (please rate whichever you do most frequently)</td>
<td>227</td>
<td>22</td>
<td>11</td>
<td>15</td>
<td>8</td>
<td>20</td>
<td>6</td>
<td>5</td>
<td>9</td>
<td>9</td>
<td>30</td>
</tr>
<tr>
<td>Using front or rear steps at home</td>
<td>168</td>
<td>30</td>
<td>25</td>
<td>19</td>
<td>15</td>
<td>33</td>
<td>6</td>
<td>8</td>
<td>15</td>
<td>6</td>
<td>40</td>
</tr>
</tbody>
</table>
Appendix 6 Service User Involvement

Background
The SAFER 1 (Support and Assessment for Fall Emergency Referrals) trial gained funding from the Department of Health (DH) policy research programme to conduct a Randomised Controlled Trial (RCT) to assess the costs and benefits of a computerised clinical decision support system for the triage of older fallers by referring appropriate patients to a falls service. The importance of public involvement in research is increasingly acknowledged and encouraged to improve research quality, relevance and accountability [1, 2, 3, 4, 5, 6, 7] and service user inclusion was planned and incorporated into trial planning from the earliest stage. In addition to the RCT a Research Professional (RP), was funded under the Clinical Research Centre (CRC) Cymru Special Project’s scheme (amount: £103,902) and supported by CRC Cymru ‘Involving People’ team. The aim of this funding was both to enhance recruitment in the trial and service user involvement in undertaking the research.

The RP was funded during the period 01/09/07-31/01/10. He worked alongside the SAFER trial co-ordinator in Wales, was a full member of the research team, under the supervision of the Principal Investigator and received advice from Involving People, the network funded in Wales to support service user involvement in health and social care research. However, SAFER 1 experienced serious delays leading to major modifications in the project timescales. These were precipitated by: the reorganisation of ambulance services in England; the complicated process involved in implementing new electronic patient records in most services; internal restructuring of partner services; and the need for increased management of the project due to partner services “Performance pressures”. The SAFER 1 study full trial began in Wales on the 19/11/09 and ran until 31/03/11. Because the recruitment of patients and involvement of service users continued to be critical to the trial’s success much of the work begun under the CRC Cymru funded project continued until the trial’s completion. This report therefore, covers the programme of service user involvement started under the CRC Cymru Special Project’s scheme until trial end. It describes how service users were included in the process of developing, undertaking and reporting on the SAFER 1 trial [8]. This report does not cover patient recruitment which is discussed more fully in the findings of the main report.

The expression ‘service user’ is used throughout this report and refers to all people who came within the inclusion criteria of the trial. It included older people who had fallen or were at risk of falling, carers and organisations whose membership included older people or represented older people.

Aim and Objective

**Aim:** To enhance service user involvement in the SAFER 1 trial.

**Objective:** To facilitate effective service user involvement throughout the study by:-
- Consulting with service user groups to gain their input at all stages of the study, from research design to dissemination of findings
- Supporting service user representatives to participate in trial management meetings
- Consulting with relevant patient/carer groups to ensure the views of older people who fall, or are at risk of falling, are included in the study
Method

Consulting with the service user group to gain their input at all stages of the study, from research design to dissemination of findings

In collaboration with Age Concern Swansea the RP established a service user reference group made up of elderly people, purposively selected by Age Concern, all of whom had experience of falling. All service users interested in the study were contacted a month before the first meeting and sent a description of the study, a summary of their role, description of their tasks during the day and a consent form. All of these were comprehensive, clearly written, with large text size, and without any scientific language or jargon. Two weeks before the meeting took place service users were contacted a second time by post to remind them of the meeting and given a contact phone number if they had any further questions. Age Concern also liaised with them to ensure they had transport to attend the meetings.

Three meetings were held on November 24th, 2008, May 26th 2009, and February 2nd 2010. Meetings were held at Swansea University between 11am-4pm. Although the venue of the first meeting had been approved by Age Concern as fully accessible, feedback indicated it was not popular with meeting attendees for being too far from the lift and toilets. Subsequent meetings were held at another university building, again checked in advance. Meetings were carefully planned to follow a format which could encourage members to feel relaxed and able to contribute to discussions. A workshop format was used with individual and group discussions which were recorded on flipcharts. Meetings had several short breaks to allow participants to take any medication. There was also an hour long lunch break to allow for refreshment and comfort. Reimbursement of travel costs, subsistence, accommodation, replacement care, and personal assistant (if required) were available to enable participation. An honorarium for time involved was also paid at the recommended rate [9]. The system for paying expenses and honorariums was managed to ensure minimum disruption by completing paperwork at the beginning of each meeting. Communication processes were discussed with service users at the first workshop and it was decided that any future contact would be first by phone, followed by a letter reminder. This process was followed in future meetings. Service users were sent a thank you letter after each workshop with a summary of the group’s contribution.

Supporting service representatives to sit on trial management meetings

Service representatives were members of the Trial Steering Committee (TSC) Trial Management Group (TMG) and Data Monitoring and Ethics Committee (DMEC). The purpose of these committees was to monitor and supervise the progress of the trial towards its interim and overall objectives.

Meetings of the TSC, TMG and DMEC were held between 2008 and 2011. Service users were recruited through TRUST, the research group for unscheduled, emergency and trauma care. Details about the SAFER 1 trial, the trial management groups and the service user role were circulated to service user members of the TRUST Advisory Group. Two service users were recruited for the TMG and one each for the TSC and DMEC. Reimbursement of travel costs, subsistence, accommodation, replacement care and personal assistant if required were available to enable participation. An honorarium for time involved at the recommended rates [9] was also paid.
Consulting with relevant patient/carer groups to ensure the views of older people who fall, or are at risk of falling, are included in undertaking the study

Meetings were held between the research team, Wales Ambulance Services NHS Trust (WAST), Age Concern Swansea, The Local Authority, Local Health Board, Accident and Emergency (Moriston) and other relevant partners to identify a relevant community based falls service. The first Falls Referral Pathway meeting was held on 29th September 2008. Age Concern Swansea was identified early on as the only service able to develop a model of care for fallers needing emergency treatment in the Swansea arm of the trial and they joined the second meeting on 17th October 2008. A further 3 meetings took place during 2008 and 7 in 2009.

Results

Consulting with the service user group to gain their input at all stages of the study, from research design to dissemination of findings

Three one-day meetings of the service user reference group were held. 25 service users were contacted and invited to attend the first meeting which was attended by nine people (seven females, two males) and the second and third by eight people.

The meetings discussed:
• development of the patient questionnaire
• patient information materials
• incentives to improve response rates
• development of interview schedules
• follow up interviews

Involvement of service users led to changes in the SAFER 1 trial protocol, including: patient information sheets, questionnaire letters, and questionnaire content.
Table 1. Service user meetings and changes made.

<table>
<thead>
<tr>
<th>Meeting number</th>
<th>Number of participants</th>
<th>Role of meeting</th>
<th>Items for discussion</th>
<th>Changes made subsequent to meeting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>9</td>
<td>To ensure that the questionnaire was easy to use while still collecting all the information needed to complete the study.</td>
<td>Questionnaire asked patients about their fall and their resulting experience</td>
<td>Questionnaire was changed in several places to make questions clearer. Letter accompanying questionnaire was rephrased to make it clearer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>To ensure documentation was easy to understand while still conveying all the relevant information needed to give informed consent</td>
<td>Documentation sent to patients such as participants information sheets and consent forms</td>
<td>The participant information sheet was rewritten with:    - Information shortened to make more approachable.    - Jargon removed in several places to make accessible    - Font and text changed to make more readable</td>
</tr>
<tr>
<td>2</td>
<td>8</td>
<td>To ensure that the qualitative interview questions were easy to follow while still collecting all the information needed to complete the study</td>
<td>Interview topic guide for qualitative interviews</td>
<td>Number of questions was reduced shortened from 6 to 4 questions</td>
</tr>
</tbody>
</table>

Each meeting required 3 days preparation time by the Research Professional (RP). Arrangements, made by telephone and confirmed in writing, took 1 ½ days to complete and a further 1 ½ days was spent on preparing for the meeting. Meeting arrangements began approximately a month before the meeting date to allow confirmation of arrangements and sufficient notice to participants. Each meeting lasted a day. Meetings were held at a pace which allowed them to take part despite any health needs. The preparation time also enabled the RP to develop a relationship with each service user which was important in supporting their participation.

Supporting service representatives to sit on trial management meetings

Service users participated in the Trial Steering Committee (TSC), Data Monitoring and Ethics Committee (DMEC) and Trial Management Group (TMG). Meeting minutes recorded attendance and the active participation of service users in all the meetings they attended. One member attended 4/4 TSC meetings and another attended 5/5 DMEC meetings during 2008-11. Two service users took part in TMG meetings. Attendance was:

<table>
<thead>
<tr>
<th></th>
<th>SU 1 / No of meetings</th>
<th>SU 2 / No of meetings</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008-9</td>
<td>2/3</td>
<td>3/3</td>
</tr>
<tr>
<td>2010*</td>
<td>0/7</td>
<td>3/7</td>
</tr>
<tr>
<td>2011*</td>
<td>0/7</td>
<td>0/3</td>
</tr>
</tbody>
</table>

*Meeting frequency increased towards end of trial. SUs were not required to attend meetings in later 2010 and 2011
Service representative inclusion in the meetings informed the general and detailed management of the trial, contributed to corporate decision-making about design, conduct & reporting of trial, such as selection of study design suitable for intervention and study characteristics; and minimised the likelihood of misleading statements. Other tasks included the selection of outcomes and the development of the analysis plan. The DMEC is an independent group responsible for monitoring the data collected by the trial & thus the safety of the intervention. Hence service representatives contributed to corporate decision-making about safety and the recruitment of patients.

Consulting with relevant patient/carer groups to ensure the views of older people who fall, or are at risk of falling, are included in undertaking the study

Through meetings between the research team, Wales Ambulance Services NHS Trust (WAST) and Swansea Age Concern, the need for a falls service was identified as a referral option for older people who fall and call 999. Age Concern and WAST agreed a Service Level Agreement to set up this referral pathway and service. From November 2008 Age Concern joined the WAST project management team meetings and contributed as the falls referral service provider. Age Concern Swansea is a local independent charity, providing services, support and advice to elderly people. As a voluntary group, representing and advocating for older people, they were able to bring to the discussions and service development their knowledge about the views of the patient group.

Although this advocacy role was not formalised they ensured elderly people’s views were heard on a range of subjects at project meetings.

Discussion

The SAFER 1 study sought to involve elderly people with experience, or risk, of falling in the trial. The views of service users were included in three ways. Firstly, individuals with experience of falling, those at risk of falling, or carers of these groups, met in a service user reference group and commented on patient information and data collection tools. Secondly, service users participated in trial management processes over the life of the study. Thirdly, the charity Age Concern brought the views of older people to the discussion and development of a falls referral service. On the continuum of involvement [10], service users in this study were involved through consultation and collaboration. Patient information materials and patient consent forms were written with input from service users in short, simple sentences and without technical vocabulary. Much care was taken in trying to strike a sensible balance between providing adequate information and too much detail.

Many of the suggestions from the service user group and from service users on the research management groups were adopted into the processes of the research project because the research team considered they improved the quality of the study [10, 15].

The variety of approaches to involve older people was taken because this can be a hard to reach group with pockets of vulnerable and difficult-to-contact people. Elderly fallers are considered harder to reach than other client groups, for reasons including age, deprivation and the possibility of shock following a recent fall. This meant that trial design and the development of information and data collection tools was important to retain the highest possible recruitment and retention rates. It was felt that an informed patient focus would improve implementation and quality of the research [11, 12, 15].

Service user involvement was time consuming, and required additional resources. Additional time was required to plan and undertake research and money was required to reimburse travel, subsistence and honorariums. The additional time and expertise required incurred costs which were resourced early in the trial with CRC Cymru funding a post from September 2007. Time was taken to establish relationships with service users. They remained actively involved throughout the study, suggesting the importance of investing in this contact in the early stage. It also suggests that service users benefit from longer term involvement and can identify their role and expertise in a study [14].
However, the Research Professional’s post was to support patient recruitment as well as service user involvement and he had to divide his time between the two aspects of his role.

The early inclusion of Age Concern as a falls referral pathway service provider offered the research team access to service users and professional expertise concerning the service user group and therefore ensured the views of older people who fall, or are at risk of falling, were included in the study. In this capacity Age Concern representatives attended project management and falls referral meetings. They contributed to many areas of trial project development as collaborative team members with a user perspective.

**Conclusion**

This study used a variety of methods to include the views of older people who had fallen, or were at risk of falling, in the trial. Early involvement of service users in the design of research materials and research questions is important in order to develop readable questionnaires and patient information which will encourage people to participate. Early recruitment of a dedicated research officer with experience of including service users was necessary to achieve the involvement of older people and should be included within a trial team. Additional time and resources should be incorporated within the research bid to resource this role and support the involvement of service users.
References


Appendix 7 Interview Guides

Paramedic Focus Group Topic Sheet 1

From SAFER 1

Thank you for taking part today. This session is to find out a bit more about your current practice and to get your thoughts and views on the new model of care proposed for the SAFER Trial

Check that we have got the consent and demographic info forms completed.

What motivated you to get involved in the study?

Have there been any other ‘new technologies’ or new equipment introduced while you’ve been a paramedic?

- How are new practices introduced?
- Issues around changing practice – any pressures?
- Attitudes towards technological developments in the health service
- Differences between attitudes of paramedics and their managers
- Barriers and motivations to new technological developments?
- Issues around using new equipment/technology
- Support for using new equipment/technology
- Operational impacts

Do new technologies sometimes bring with them additional decision making for paramedics?

- Adapting to this
- Resistance?
- Time to adopt new processes?

How do you deal with calls from older fallers at the moment?

- options available to the paramedic
- links to other services to support older fallers
- explore issues around deciding to leave at home or convey
- any frustrations with the current system
- Risks with the current system – to patient
- Risks with the current system – to paramedic (confidence to leave patients at home)

Do you think that having access to a falls pathway will make a difference?

- To the patient
- To you
- Suitability of this patient group for the new care pathway
We’re proposing that you use an electronic PCR to take down older fallers details, rather than a paper one. Does this raise any thoughts or concerns?

- Explore clinical documentation (purpose and value)

We asked at the beginning about your motivations for getting involved. We wondered what you thought your colleagues would make of you taking part in the study and using the new kit?

We’ve come to the end of this focus group, thank you all for your contributions.

Earlier version

**Check that we have all the consent and demographic info forms**

Drawing on published research literature and experience from the SAFER 1 Trial each interview/group will cover:

- General views concerning technological developments in the health service
  - Attitudes to using the electronic patient report form

- Experience of use/supporting use

- Attitudes to CCDS:
  - How the CCDS was introduced and supported
  - training/clinical support
  - ergonomic issues (ease of use/practicality)
  - organisational factors
  - cross-organisational working

- issues relating to the emergency setting
  - suitability of the patient group
  - views about the value and purpose of clinical documentation

- Operational impact

- impact on role
  - decision making processes
  - perceptions of autonomy and risk
SAFER 1 – QUESTIONS (INTERVENTION GROUP)

1. Describe implementation of CCDS - to tell the story of how the technology is introduced and supported

Do you think the introduction of the ePCR and CDS was handled well?
- What went well in the preparation and training?
- What went less well?
- What was your experience of using the ePCR/CDS system once the trial went live – what worked, what didn’t, teething troubles, learning curves – what is the story of getting used to using the CDS/ePCR

Looking back, do you feel the ePCR and CDS training was adequate and useful? What if anything do you think was missing from the training? Would you have liked more training and/or supervised practise – if so, in what way?

Do you think the on-going support has been adequate? From the SAFER team, WAST managers, technical?

Have you reported any technical problems? If so, to whom?

Do you generally manage to be allocated to a vehicle that is fitted with SAFER 1 equipment?

Are there any operational issues that affect your use/non use of the CDS or ePCR?

2. Examine how paramedics use CDS

Roughly how many older patients who have fallen have you dealt with since the study commenced? What proportion of these have you used the SAFER 1 CDS? What were the reasons for not using the CDS for the other cases?

What do you find good about using the CDS?

What do you find less good or difficult? How could the CDS be improved to address these difficulties?

What has been your experience of the clinical content in the CDS? How have you found the question and answer prompts? How have you found the examination prompts? How have you found the advice and educational content included in the CDS? In what ways could the clinical content be improved?

3. To assess the impact of the introduction of CDS on practice through measures of processes of care

Does using the ePCR and CDS make a difference to the job length – and in what way?

Have there been any occasions when you have chosen to not use the ePCR or CDS because you feared it would take too long?

Has the CDS system changed or made a difference to the way you work? Do you think it has affected whether or not you transfer patients to hospital? If so, in what way?

Do you think it has affected how you practise more generally, i.e. for patients who have non-fall related problems? If so, in what way?

4. To explore factors influencing paramedics' responses to the introduction of CDS

Do you find the CDS easy to use?

Are there any issues with carrying the Table PC about or maintaining a connection to the internet?

What about the printer? Is the printer easy to use?

Do you find the questions on the CDS useful?

Have you had any technical problems with it, if so please describe them?

Are you more likely to use the ePCR or the CDS?

Further feedback

Please offer any other feedback, good or bad, on the equipment, the processes involved or the overall Trial – please be as honest and critical as you wish!
Trial-end semi-structured interview guide: For use with paramedics

1) To start off I’m interested in finding out a bit about how you got involved.
   • Can you tell me how you found out about the study?
   • What was it about the study that made you want to take part?
   • What were you asked to do for the study that was different to what you were doing already?

2) Can you tell me about how you were trained and who by?
   • Was this enough training – or too little/too much?
   • Once you got the software how long was it before you started using it?
     (PROMPT: explore any delay or non-usage)

3) On a practical level, how have you found using the different bits of kit involved? (Explore pros and cons, ease of use, practicality of...)
   • The computer, printer and charger
   • The internet connection
   • Any other ease of use or practical issues with using the system?

4) How do you find using the electronic patient report forms?
   • How do you feel about the shift to electronic patient report forms?
   • Do you think there are any advantages to recording patient information electronically?
   • Disadvantages?
   • Is it practical to use? Do/did you use it?
   • Does it affect on-scene time?
   • Do you feel there’s a difference between having a paper or an electronic record? Which do you prefer and why?
   • In practice when and where are ePCRs completed? (PROMPT: in EEAS find out who completed the ePCRs when falls assessments were undertaken)

5) How did you find using the falls assessment software?
   • How did you decide when to use the falls assessment software?
   • Did you use it with all older fallers or just some?
   • Is it practical to use? Did you use it? Did you find it useful?
   • How does it affect on-scene time?
   • Has it made any difference to your decision making on-scene?
   • Did you follow the recommendations that the software came up with?
   • Did it help you decide whether to take a patient to hospital or refer them to the falls service?
   • Has it made any difference to the way you work?
   • Did it make you feel more, or less empowered professionally
   • Did you feel it added to or reduced the risks associated with the job you do?
   • If you could, would you choose to use the falls assessment software again?
   • In practice when and where did you complete the falls assessment software?
6) Do you think that using the technology impacts on the quality of your interaction with the patient?
- How has it gone down with patients?
- Have any patients been concerned about data security and confidentiality?
- Do you have any concerns about this?
- Do you think that the falls assessment software was suitable for use with older fallers as a patient group?

7) I’d like to find out about any support that was available to you while you were taking part in the study.
- Was there any technical support available if you needed it?
- Was there any operational or clinical support available if you needed it?
- What did you feel the attitude of your managers was to you using the falls assessment software?
- Did that have an impact on you using it?
- What was the attitude of other paramedics towards you using the falls assessment software?
- Does using the falls assessment software affect the way you work with other organisations at all? (E.g. falls services, hospitals, GPs)

8) More generally, what do you think about the introduction of computerised technology in the health and ambulance service?
- Do you feel it’s changed your role or at all?
- How has it affected the way you work?
- Do you feel that technology either improves or undermines what you do as a professional?

9) Any recommendations for how the falls assessment software and the way it’s implemented could be improved for paramedics in the future?

10) Is there anything else about the study that you think might be of interest, or anything you’d like to tell me about, or ask me?

**Demographic info**

- Just to finish off, can I ask how long you’ve been in service?
- And how long you’ve been a qualified paramedic?
- How would you describe your level of IT skill before the trial?
- And now?
- And finally, how young are you?!

That’s the last of the interview questions, but can I just ask if you’ve had a chance to sign your consent form and pop it in the post yet?

Many thanks for taking the time to talk to me today
Trial-end topic guide for interviews/focus groups:
For use with key ambulance service personnel and other stakeholders

Preparation:
- Introduce yourself
- Check consent forms have been received/signed/returned
- Press record
- Read introduction below (important) and move onto questions/prompts

Introduction: Thank you for taking the time to talk to me/us today. Now that we’ve come to the end of the data collection phase of the project we’d like to get your feedback on the SAFER 1 intervention. That covers a few different elements including: training, computer hardware, electronic patient report form software, computerised clinical decision support software for assessing older fallers and the falls referral pathway.

1) To start off with I’m interested in finding out what you thought about the intervention as a whole?
   - How does it compare or differ to current practice?
   - Do you think it’s made a difference to how the intervention group paramedics work? In what way? If not, why not?
   - What sort of feedback, if any, did you get from paramedics about the intervention as a whole?
   - Was there feedback from others in your organisation?
   - Do you think there are any benefits to working in this way?
   - Do you think there are any drawbacks to working in this way?
   - What do you think of the intervention overall?

2) Do you think that the SAFER 1 intervention was suitable for your organisation? In what ways?
   - Do you think that there are things about your organisation that affected whether the intervention was used or not? In what ways? (culture, service developments, pressures etc)
   - Did anything going on outside your organisation affect whether the intervention was used or not? (other organisations or developments, explore background context)

3) What cross-organisational working arrangements were in place to support this intervention?
   - Falls service, A&E, GPs, others?
   - How has cross-organisational working gone in relation to this intervention?
   - Do you think that cross-organisational factors have affected whether the intervention was used or not?

4) I’d like to find out what your views are in relation to the implementation of the intervention?
   - Do you think there was there enough training provided to paramedics?
   - Was there enough support provided to paramedics? (technical/operational/clinical, other)
• Was the kit practical to use? (Explore pros and cons, ease of use of...)  
  a. The computer, printer and charger  
  b. The internet connection  
  c. Any other ease of use or practical issues with using the system?  
• If this intervention were rolled out elsewhere what do you think could be done, if anything, to improve implementation?

5) How do you feel about paramedics collecting patient data on electronic patient report forms rather than paper ones?  
• Do you think there are any advantages or disadvantages to recording patient information electronically?  
  a. For the patient  
  b. For the paramedic  
  c. For the ambulance service  
• Do you think that using technology impacts on the quality of contact with the patient?  
• Do you have any concerns about data security and confidentiality?  
  a. For the patient  
  b. For the paramedic  
  c. For the ambulance service  

6) I want to find out a bit more about your views on the falls assessment software element of the intervention (also known as computerised decision support software)  
• How do you feel about falls assessment software being used to support patient assessment?  
• Do you think it has a role in helping paramedics decide whether to convey patients to hospital or refer them to community based services?  
• Do you think there are any advantages or disadvantages to using falls assessment software?  
  a. For the patient  
  b. For the paramedic  
  c. For the ambulance service  
• Do you think that the falls assessment software was suitable for use with older fallers as a patient group?  
• Do you think that there is a role for computerised decision support for conditions other than a fall?  

7) Finally, is there anything else about the study that you think might be of interest, or anything you’d like to tell me about, or ask me?
EEAS Paramedic Interview Guide

What motivated you to get involved in the study?

Have there been any other ‘new technologies’ or new equipment introduced while you’ve been a paramedic?

- How are new practices introduced?
- Issues around changing practice – any pressures?
- Attitudes towards technological developments in the health service
- Differences between attitudes of paramedics and their managers
- Barriers and motivations to new technological developments?
- Issues around using new equipment/technology
- Support for using new equipment/technology
- Operational impacts

Do new technologies sometimes bring with them additional decision making for paramedics?

- Adapting to this
- Resistance?
- Time to adopt new processes?

How do you deal with calls from older fallers at the moment?

- options available to the paramedic
- links to other services to support older fallers
- explore issues around deciding to leave at home or convey
- any frustrations with the current system
- Risks with the current system – to patient
- Risks with the current system – to paramedic (confidence to leave patients at home)

Do you think that having access to a falls pathway will make a difference?

- To the patient
- To you
- Suitability of this patient group for the new care pathway

We’re proposing that you use an electronic PCR to take down older fallers details, rather than a paper one. Does this raise any thoughts or concerns?

- Explore clinical documentation (purpose and value)

I asked at the beginning about your motivations for getting involved. I wondered what you thought your colleagues would make of you taking part in the study and using the new kit?

I’ve come to the end of this interview, thank you all for your contributions.
SAFER 1 Study

Participant Information Sheet

What is the study about?

The study will help to find out what works best for patients aged 65 or older when a 999 call is made. It will help us test a computer that supports paramedics to make decisions about patient care, in particular whether the patient needs to be taken to the Accident and Emergency Department (A&E) or can be left at home with a referral to a service that is not hospital based.

Why have I been chosen?

We are writing to people aged 65 or over that have recently called 999 and been attended by one of the paramedics who are taking part in the study.

What will happen if I am included?

In about two weeks time we will send you a questionnaire which we would like you to complete and send back to us. We will be asking about your general health and your views about the care you received. We have been careful to keep the questionnaire as short as possible. If you have difficulty completing the questionnaire, we can help you to complete it by telephone or in person – please call 01792 513432 to speak to
a member of the SAFER 1 team to arrange this. If there is someone who is caring for you (a relative or friend), he or she can complete the questionnaire with you. If someone does help you to fill out the questionnaire then we would like to know and there is a tick box on the front page for you to fill in.

**Medical Contacts**

If you agree to be included, we would also like to track any further 999 calls, visits to A&E or hospital stays during the one-month period following this 999 call. You will not have to do anything.

**Do I have to be included?**

No, you do not have to be included. If you do not wish to be included please complete the relevant sections of the opt-out form enclosed and return it to us in the FREEPOST envelope (no stamp required). You can participate in either part of the study, or all of the study (follow up of medical records and questionnaire completion). Just let us know if you do not wish to participate in either part or both by completing the form and sending it back to us in the FREEPOST envelope – there is no need to use a stamp for this.

**Will my care be affected?**

There will be no impact on the care you receive, whether you are included or not.

**What are the benefits to being included?**

The study is helping to improve care for older people who have a health emergency. It is testing whether some patients do better if help is provided at home rather than at A&E after a 999 call. If you are included in this study we will have more chance of understanding what works better for patients.
Who will see my information?

All information collected about you during the course of the study will be kept strictly confidential. Any information with your name or other identifiable details will only be seen by members of the research team.

What if there is a problem?

We do not believe there will be any problems arising from your being included in this study. However, if there is anything you are not happy with; please contact the study Co-ordinator (details below). If you remain unhappy and wish to complain formally, please do so through the NHS complaints procedure.

What if I change my mind?

If you change your mind and do not wish to continue in the study, you are free to withdraw at any time. Please let the study co-ordinator know. Your care will remain unaffected.

Who is organising and funding the research?

The study is organised by researchers in the School of Medicine at Swansea University, in collaboration with the Welsh Ambulance Services NHS Trust and the East of England Ambulance Service NHS Trust. It is funded by the Department of Health.

Who has reviewed the study?

The study has been reviewed by the Research Ethics Committee for Wales.

Contact Details

Study Co-ordinator: Claire Williams, School of Medicine, Swansea University

Telephone: 01792 606685
Appendix 9 **Systematic Review Search Terms**

The literature search was conducted by combining the search terms as indicated in the table below and MeSH terms were identified and used where appropriate. An asterisk indicates where a word was truncated for the search.

<table>
<thead>
<tr>
<th>Computerised clinical decision support</th>
<th>Population</th>
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<tbody>
<tr>
<td>Computer assisted decision making</td>
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<tr>
<td>Computer assisted diagnosis</td>
<td>pre-hospital</td>
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<tr>
<td>Computer* medical decision support</td>
<td>Paramedic*</td>
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<tr>
<td>Computer assisted medical decision support</td>
<td>Emergency</td>
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<tr>
<td>Computer* clinical decision support</td>
<td>Ambulance</td>
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<tr>
<td>CCDSS</td>
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<tr>
<td>Computer* decision support system</td>
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<tr>
<td>CDSS</td>
<td>urgent</td>
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<tr>
<td>Computer* clinical decision support system</td>
<td>out of hours</td>
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<tr>
<td>CCDSS</td>
<td>out-of-hours</td>
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<tr>
<td>Decision support techniques</td>
<td>Mobile</td>
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<tr>
<td>Decision analysis, computer assisted</td>
<td>Healthcare</td>
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<tr>
<td>Information technology</td>
<td>Delivery of healthcare</td>
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<tr>
<td>Decision-making, computer assisted</td>
<td>Allied Health Personnel</td>
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<tr>
<td>Computer based decision support</td>
<td>Telemedicine</td>
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<td>Computer assisted instruction</td>
<td>After Hours Care</td>
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<tr>
<td>Medical decision making, computer assisted</td>
<td>Paramedic Personnel</td>
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<td>Emergency medical technician*</td>
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<td>Community health aides</td>
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<td>Hand-held computer-based decision support</td>
<td>Mobile health practitioner</td>
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<td>Clinical decision support model</td>
<td>Medical care</td>
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<td>Electronic decision support</td>
<td>Emergency health personnel</td>
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<td>Computer/electronic/PDA/Handheld/hand-</td>
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<tr>
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<td>Decision trees</td>
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<td>Computerised clinical decision support</td>
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<td>Unscheduled triage</td>
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<td>999</td>
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<td>Emergency department</td>
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<td>A&amp;E</td>
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<td>Rapid response vehicle</td>
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<td>Mobile emergency unit</td>
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<td>Mobile emergency care</td>
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<td>Emergency service</td>
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<td>Emergency medical service</td>
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<td>Hotlines</td>
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<td>Emergency health personnel</td>
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<td>Emergency triage</td>
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These supplement the analysis presented in Table 6 of Chapter 4.

Event 1 = death

Event 2 = death or inpatient admission
Event 3 = death, inpatient admission or emergency department attendance

Event 4 = death, inpatient admission, emergency department attendance or 999 call
Time to first fall-specific event (1)

Event 1 = death or admission related to a fracture

Time to first fall-specific event (2)

Event 2 = death, fall-related admission or emergency department attendance
Event 3 = death, fall-related admission, emergency department attendance or 999 call
Appendix 11  TSC & DMEC Members

**Trial Steering Committee (TSC)**

*Chair*
Chris Salisbury  
Professor of Primary Health Care, Bristol University

*A&E Consultant*
Dr Suzanne Wyatt  
Clinical Director of Unscheduled Care,  
University Hospital of Wales, Cardiff

*Clinician*
Mr Chris Hartley- Sharpe  
Ambulance Operations Manager, London Ambulance Service

*Patient Representative*
Greg Morgan

*Observer*
Simon Bevan  
Programme Manager, NETSCC, Southampton
Ceri Jones  
Department of Research & Innovation, Swansea University
Helen Snooks  
Professor in Health Services Research, Swansea University

**Data Monitoring Ethics Committee (DMEC)**

*Chair*
Dr Kerry Hood  
Director of South East Wales Trials Unit, Cardiff University

*Statistician*
Dr John Belcher  
Senior Lecturer in Biostatistics, Keele University

*Clinician*
Dr Tony Bayer  
Senior Lecturer and Acting Head of Geriatric Medicine,  
Cardiff University

*Patient Representative*
Colin Thomson

*Observer*
Wai-Yee Cheung  
Senior Lecturer, Swansea University
Antonio Sanchez-Vasquez  
Trial Co-ordinator, Swansea University
Richard Whitfield  
Research & Development Manager,  
Welsh Ambulance Services NHS Trust